DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

42 CFR Parts 409, 410, 418, 440, 484, 485 and 488

[CMS-3819-P]

RIN 0938-AG81

Medicare and Medicaid Program: Conditions of Participation for Home Health Agencies

AGENCY: Centers for Medicare and Medicaid Services (CMS), HHS.

ACTION: Proposed rule.

SUMMARY: This proposed rule would revise the current conditions of participation (CoPs) that home health agencies (HHAs) must meet in order to participate in the Medicare and Medicaid programs. The proposed requirements would focus on the care delivered to patients by home health agencies, reflect an interdisciplinary view of patient care, allow home health agencies greater flexibility in meeting quality care standards, and eliminate unnecessary procedural requirements. These changes are an integral part of our overall effort to achieve broad-based, measurable improvements in the quality of care furnished through the Medicare and Medicaid programs, while at the same time eliminating unnecessary procedural burdens on providers.

DATES: To be assured consideration, comments must be received at one of the addresses provided below, no later than 5 p.m. on **[**insert date 60 days after date of publication in the **Federal Register]**.

ADDRESSES: In commenting, please refer to file code CMS-3819-P. Because of staff and resource limitations, we cannot accept comments by facsimile (FAX) transmission.

You may submit comments in one of four ways (please choose only one of the ways listed):

1. Electronically. You may submit electronic comments on this regulation to http://www.regulations.gov. Follow the instructions under the more search options tab.

2. By regular mail. You may mail written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-3819-P,

P.O. Box 8016,

Baltimore, MD 21244-8016.

Please allow sufficient time for mailed comments to be received before the close of the comment period.

3. By express or overnight mail. You may send written comments to the following address ONLY:

Centers for Medicare & Medicaid Services,

Department of Health and Human Services,

Attention: CMS-3819-P,

Mail Stop C4-26-05,

7500 Security Boulevard,

Baltimore, MD 21244-1850.

4. By hand or courier. If you prefer, you may deliver (by hand or courier) your

written comments (one original) before the close of the comment period to either of the following addresses:

a. Room 445-G, Hubert H. Humphrey Building,

200 Independence Avenue, SW.,

Washington, DC 20201

(Because access to the interior of the Hubert H. Humphrey Building is not readily available to persons without Federal Government identification, commenters are encouraged to leave their comments in the CMS drop slots located in the main lobby of the building. A stamp-in clock is available for persons wishing to retain a proof of filing by stamping in and retaining an extra copy of the comments being filed.)

b. 7500 Security Boulevard,

Baltimore, MD 21244-1850.

If you intend to deliver your comments to the Baltimore address, please call telephone number (410) 786-9994 in advance to schedule your arrival with one of our staff members.

Comments mailed to the addresses indicated as appropriate for hand or courier delivery may be delayed and received after the comment period.

Submission of comments on paperwork requirements. You may submit comments on this document's paperwork requirements by following the instructions at the end of the "Collection of Information Requirements" section in this document.

For information on viewing public comments, see the beginning of the "SUPPLEMENTARY INFORMATION" section.

FOR FURTHER INFORMATION CONTACT:

Danielle Shearer (410) 786-6617.

Jacqueline Leach (410) 786-4282.

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SUPPLEMENTARY INFORMATION:

Inspection of Public Comments: All comments received before the close of the comment period are available for viewing by the public, including any personally identifiable or confidential business information that is included in a comment. We post all comments received before the close of the comment period on the following Web site as soon as possible after they have been received: http://www.regulations.gov. Follow the search instructions on that Web site to view public comments.

Comments received timely will also be available for public inspection as they are received, generally beginning approximately 3 weeks after publication of a document, at the headquarters of the Centers for Medicare & Medicaid Services, 7500 Security Boulevard, Baltimore, Maryland 21244, Monday through Friday of each week from 8:30 a.m. to 4 p.m. To schedule an appointment to view public comments, phone 1-800-743-3951.

I. Introduction

As the single largest payer for health care services in the United States, the Federal government assumes a critical responsibility for the delivery and quality of care furnished under its programs. Historically, we have adopted a quality assurance approach that has been directed toward identifying health care providers that furnish poor quality

care or fail to meet minimum Federal standards. Facilities not meeting requirements would either correct the inappropriate practice(s) or would be terminated from participation in the Medicare or Medicaid programs. We have found that this problem-focused approach has inherent limits. Ensuring quality through the enforcement of prescriptive health and safety standards, rather than improving the quality of care for all patients, has resulted in expending much of our resources on dealing with marginal providers, rather than on stimulating broad-based improvements in the quality of care delivered to all patients.

Obtaining quality health care for Federal beneficiaries from CMS-certified providers and suppliers requires taking advantage of continuing advances in the health care delivery field. As a result, we are proposing to revise the home health agency requirements to focus on a patient-centered, data-driven, outcome-oriented process that promotes high quality patient care at all times for all patients. We have developed a proposed set of fundamental requirements for Home Health Agency (HHA) services that would encompass patient rights, comprehensive patient assessment, and patient care planning and coordination by an interdisciplinary team. Overarching these requirements would be a quality assessment and performance improvement program that would build on the philosophy that a provider's own quality management system is key to improved patient care performance. The objective would be to achieve a balanced regulatory approach by ensuring that a HHA furnished health care that met essential health and quality standards, while ensuring that it monitored and improved its own performance.

Health Disparities

In 1985, the Secretary of the Department of Health and Human Services issued a landmark report which revealed large and persistent gaps in health status among Americans of different racial and ethnic groups and served as an impetus for addressing health inequalities for racial and ethnic minorities in the U.S. This report led to the establishment of the Office of Minority Health (OMH) within the Department of Health and Human Services (HHS), with a mission to address these disparities throughout the Nation. National concerns for these differences in health outcomes between populations, termed health disparities, and the associated excess mortality and morbidity rates have been expressed as a high priority in national health status reviews, including Healthy People 2000, 2010, and 2020. In 2011, HHS also issued the HHS Action Plan to Reduce Racial and Ethnic Health Disparities (found at http://www.minorityhealth.hhs.gov/npa/templates/content.aspx?lvl=1&lvlid=33&ID=285).

Since this time, research has extensively documented the pervasiveness of disparities in health care and has led to the acknowledgement of disparities as a national problem, expansion of populations identified as vulnerable, development of programs and strategies to reduce disparities for vulnerable populations, and the emergence of new leadership to address these disparities. Vulnerable populations include groups of people who have systematically experienced greater obstacles to health based on their racial or ethnic groups; religion; socioeconomic status; gender; age; mental health; cognitive, sensory, or physical disability; sexual orientation or gender identity; geographic location; or other characteristics historically linked to discrimination or exclusion. We are aware

that other populations at risk may include pregnant women, infants, persons with limited English proficiency (LEP), and persons with disabilities (for example, visual, hearing, cognitive or perceptual impairments) or special health care needs.

Although there has been much attention at the national level given to ideas for reducing health disparities in vulnerable populations, we remain vigilant in our efforts to improve health care quality for all persons by improving health care access and by eliminating real and perceived barriers to care that may contribute to less than optimal health outcomes for vulnerable populations. Despite the long-term implementation of some strategies like providing oral interpretation services to persons with LEP in hospitals, effective communication and its impact on health care outcomes continues to be in the forefront of the national discussion.

We believe some aspects of this proposed rule, such as requiring patient rights to be explained to a patient in the language and manner that he or she understands, would address the needs of vulnerable populations and contribute to eliminating health disparities. We are specifically requesting comments in regard to how our proposed requirements could be used to address disparities.

II. Background

A. The Home Health Benefit

Home health services are covered for the elderly and disabled under the Hospital Insurance (Part A) and Supplemental Medical Insurance (Part B) benefits of the Medicare program, and are described in section 1861(m) of the Social Security Act (the Act). These services, provided under a plan of care that is established and periodically

reviewed by a physician, must be furnished by, or under arrangement with, an HHA that participates in the Medicare or Medicaid programs, and are provided on a visiting basis in the beneficiary's home. Services may include the following:

- Part-time or intermittent skilled nursing care furnished by or under the supervision of a registered professional nurse.
- Physical therapy, speech-language pathology, and occupational therapy.
- Medical social services under the direction of a physician.
- Part-time or intermittent home health aide services.
- Medical supplies (other than drugs and biologicals) and durable medical equipment.
- Services of interns and residents if the HHA is owned by or affiliated with a hospital that has an approved medical education program.
- Services at hospitals, skilled nursing facilities, or rehabilitation centers when they involve equipment too cumbersome to bring to the home.

Under the authority of sections 1861(o) and 1891 of the Act, the Secretary has established in regulations the requirements that an HHA must meet to participate in the Medicare program. These requirements are set forth in regulations at 42 CFR part 484, Home Health Services. Current regulations at 42 CFR 440.70(d) specify that HHAs participating in the Medicaid program must also meet the Medicare Conditions of Participation (CoPs). Section 1861(o)(6) of the Act requires that an HHA must meet the CoPs specified in section 1891(a) of the Act, and other CoPs as the Secretary finds necessary in the interest of the health and safety of patients. Section 1891(a) of the Act establishes specific requirements for HHAs in several areas, including patient rights, home

health aide training and competency, and compliance with applicable federal, state, and local laws. The CoPs for HHAs protect all individuals under the HHA's care, unless a requirement is specifically limited to Medicare beneficiaries. Section 1861(o) of the Social Security Act (the Act) describes an HHA for purposes of participation in the Medicare program in broadly descriptive terms. All the requirements are stated generally as applicable to the HHA's overall activity, and not specifically to the Medicare patient. This provision, which was reaffirmed by Congress in the OBRA 1987 amendments to section 1891(a) of the Act, has been in the law since the inception of the Medicare program, and CMS' interpretation of it has remained the same. Under section 1891(b) of the Act, the Secretary is responsible for assuring that the CoPs, and their enforcement, are adequate to protect the health and safety of individuals under the care of an HHA, and to promote the effective and efficient use of Medicare funds. To implement this requirement, State survey agencies and CMS-approved accrediting organizations conduct surveys of HHAs to determine whether they are complying with the conditions of participation.

B. Previous HHA Conditions of Participation Rules

On March 10, 1997 (62 FR 11004), we published a proposed rule, entitled, "Revision of the Conditions of Participation for Home Health Agencies and Use of the Outcome and Assessment Information Set (OASIS) as Part of the Revised Conditions of Participation for Home Health Agencies," that would have revised the entire set of HHA CoPs. Due to the significant volume of public comments and the rapidly changing nature of the HHA industry at that time, this rule, in its entirety, was never finalized.

Rather than finalizing all portions of the March 1997 rule, we published a final regulation (64 FR 3764, January 25, 1999) that only finalized the OASIS regulations. The January 1999 final rule required that each patient receive from the HHA a patient-specific, comprehensive assessment that identifies the patient's medical, nursing, rehabilitation, social, and discharge planning needs.

We also issued an interim final rule with comment period on January 25, 1999 (64 FR 3748) that required HHAs to use the Outcome and Assessment Information Set (OASIS) data collection instrument that standardizes parts of the assessment. This rule also required HHAs to transmit the data to CMS. Section 1891(c)(2)(C) and section 1891(d)(1) of the Social Security Act (the Act) require the Secretary to establish a standardized assessment instrument for measuring the quality of care and services furnished by HHAs. The OASIS data collection instrument and data transmission rule was finalized on December 23, 2005 (70 FR 76199) in order to implement this statutory requirement.

Although the OASIS requirements were finalized in separate rules, we intended to proceed with another rule to finalize the remainder of the requirements of the March 1997 proposed rule. However, Section 902 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) added section 1871(a)(3) to the Act. This section provided that, effective December 8, 2003, the Secretary, in consultation with the Director of the Office of Management and Budget (OMB), would have to establish and publish regular timelines for the publication of Medicare proposed regulations based on the previous publication of Medicare proposed or interim final regulations. Section 902 of the

MMA further provided that the timeline could vary among different regulations, but could not be longer than 3 years, except under exceptional circumstances. Pursuant to the MMA, we issued a notice implementing this provision in the **Federal Register** on December 30, 2004 (69 FR 78442). In that notice, we interpreted section 902 as rendering ineffective any proposed Medicare regulations that had been outstanding for 3 years or more as of December 8, 2003; this included the HHA CoPs. Therefore, out of an abundance of caution, we decided not to finalize the remaining provisions of the March 10, 1997 proposed rule, but begin rulemaking again.

C. Transforming the HHA Conditions of Participation

Before we began development of new proposed CoPs for Medicare and Medicaid participating HHAs, we received recommendations from home health providers, professional associations and practitioner communities, consumer advocates and state and other governmental agencies with an interest or responsibility in HHA regulation and oversight. We also took into account the comments that were submitted by the public on the March 1997 proposed rule and suggestions submitted by the HHA industry in the summer of 2011, as well as developments since that time within the industry. In light of this information, we have used the following principles to assist in the development of the new HHA CoPs:

- Develop a more continuous, integrated care process across all aspects of home health services, based on a patient-centered assessment, care planning, service delivery, and quality assessment and performance improvement.
- Use a patient-centered, interdisciplinary approach that recognizes the contributions

of various skilled professionals and their interactions with each other to meet the patient's needs. Stress quality improvements by incorporating an outcome-oriented, data-driven quality assessment and performance improvement program specific to each HHA.

- Eliminate the focus on administrative process requirements that lack adequate consensus or evidence that they are predictive of either achieving clinically relevant outcomes for patients or preventing harmful outcomes for patients.
- Safeguard patient rights.

Based on these principles, we are proposing new HHA CoPs that would revise or eliminate many current requirements and would focus provider efforts on the services delivered to the patient, the quality of care furnished by the HHA, and quality assessment and performance improvement efforts. We propose to establish the following four CoPs (in addition to retaining the current requirements at §484.55, Comprehensive assessment of patients):

- "Patient rights" would emphasize a HHA's responsibility to respect and promote the rights of each home health patient.
- "Care planning, coordination of services, and quality of care" would incorporate the interdisciplinary team approach to provide home health services focusing on the care planning, coordination of services, and quality of care processes.
- "Quality assessment and performance improvement" (QAPI) would charge each HHA with responsibility for carrying out an ongoing quality assessment, incorporating data-driven goals, and an evidence-based performance improvement

program of its own design to affect continuing improvement in the quality of care furnished to its patients.

- "Infection prevention and control" would require HHAs to follow accepted standards of practice to prevent and control the transmission of infectious diseases and to educate staff, patients, and family members or other caregivers on these accepted standards. The HHA would be required to incorporate an infection control component into its QAPI program.

In the revised CoPs, we propose to retain and/or include process-oriented requirements that are predictive of ensuring desired outcomes. We propose to eliminate many of the process details from the current requirements where they do not achieve this goal. For example, we propose to remove the process requirement under current §484.12(c) that a HHA and its staff comply with accepted professional standards and principles. Instead, we propose to modify this requirement by referencing current clinical practice guidelines and professional standards specific to home care (for example, the ANA Scope and Standards of Practice for Home Health Nurses) as factors to be considered in the HHA's overall QAPI program. We are not proposing to incorporate by reference any specific clinical practice guidelines or professional standards of practice. The HHA would be responsible for identifying its own performance problems through its QAPI program, addressing them, and continuously striving to improve the quality of clinical care, patient outcomes and satisfaction, as well as efficiency and economy. We also propose to remove the requirements that the HHA send a summary of care to the attending physician at least once every 60 days, that the HHA have a group of professional personnel to advise its

operation, and that the HHA conduct a quarterly evaluation of its program via chart reviews.

We believe that the proposed CoPs, which are based on the principles of continuous and ongoing quality assessment and performance improvement, reflect a fundamental change in our regulatory approach -- a change that to a large extent establishes a shared commitment between CMS and HHA providers to achieve improvements in the quality of care furnished to HHA patients. This approach has already been implemented through the Conditions of Participation/Conditions for Coverage (CoPs/CfCs) for end-stage renal disease suppliers, hospitals, hospices, transplant centers, and organ procurement organizations. The proposed HHA CoPs would prompt HHAs to invest internally in their responsibility to continuously improve performance, rather than relying solely on an external approach in which prescriptive federal requirements are enforced through the survey process. We anticipate that this patient-centered, outcome-oriented approach will result in an enhanced working relationship between state survey agencies and HHAs. These requirements would provide a basis for improved performance that will help to ensure that quality home health care is provided to all patients.

These proposed regulations contain two critical improvements that would support and extend our focus on patient-centered, outcome-oriented surveys. First, the proposed regulations are designed to enable surveyors to look at outcomes of care, because the regulations would specify that each individual receive the care which his or her assessed needs demonstrate is necessary, rather than focusing simply on the services and processes that must be in place. Second, the addition of a strong QAPI requirement would not only

stimulate the HHA to continuously monitor its performance and find opportunities for improvement, it would also afford the surveyor the ability to assess how effectively the provider was pursuing a continuous quality improvement agenda. All of the changes would be directed toward improving patient-centered outcomes of care, and engaging the patient, family and physician in the care planning and care delivery processes. We believe that the overall approach of the proposed CoPs would provide HHAs with greatly enhanced flexibility. At the same time, the proposed requirement for a program of continuous quality assessment and performance improvement would increase performance expectations for HHAs, in terms of achieving needed and desired outcomes for patients and increasing patient satisfaction with services provided.

III. Provisions of the Proposed Rule

A. Overview

Under our proposal, the HHA CoPs would continue to be set forth in regulations under 42 CFR part 484. However, since many of the current requirements in part 484 would be revised, consolidated with other requirements, or eliminated, this proposed rule would make extensive changes in the current organizational scheme. The most significant change would be grouping together all CoPs directly related to patient care and place them near the beginning of part 484. Regulations concerning the organization and administration of a HHA would follow in a separate subpart titled “Organizational Environment.” This format would be better in keeping with the patient-centered orientation of these regulations, and would reinforce our view that patient assessment, care planning, and quality assessment and performance improvement efforts are central to the delivery of high quality

care.

B. Proposed Subpart A, General Provisions

We propose to reorganize this section to clarify the basis and scope of this part. Specifically, §484.1 would set out the statutory authority for these regulations. Part 484 is based on sections 1861(o) and 1891 of the Act, which establish the conditions that a HHA must meet in order to participate in the Medicare program. Part 484 is also based on section 1861(z) of the Act, which specifies the institutional planning standards that HHAs must meet. These provisions serve as the basis for survey activities for the purposes of determining whether an agency meets the requirements for participation in Medicare. Currently, §484.1(a)(3) refers to section 1895 of the Act, which serves as the basis for the establishment of a prospective payment system for home health services covered under Medicare. This section of the Act is already cited at §484.200 as the basis for subpart E of this part, Prospective Payment System for Home Health Agencies, therefore, we propose to delete §484.1(a)(3).

At §484.2, we propose to clarify some of the definitions for terms used in the HHA CoPs. The definition for "branch office" would be modified by adding the requirement that the parent agency offer more than the sharing of services; specifically, that it provide supervision and administrative control of branches on a daily basis to the extent that the branch depends upon the parent agency's supervision and administrative functions in order to meet the CoPs, and could not do so as an independent entity. The supervision and administrative control would have to assure that the quality and scope of items and services provided was of the highest practicable level for all patients, so as to meet their medical,

nursing, and rehabilitative needs. Though the definition would no longer require the branch office to be "sufficiently close," the parent agency would have to be available to meet the needs of any situation and respond to issues that could arise with respect to patient care or administration of the agency. A violation of a CoP in one branch office would apply to the entire HHA.

We also propose minor changes in the language of the current definitions for "clinical note," "parent home health agency," "proprietary agency," and "subdivision." These changes would achieve greater clarity within these definitions and achieve consistency with the other definitions contained in this section.

We also propose to eliminate current definitions of the terms "bylaws" and "supervision." We believe the meanings of these terms are self-evident, and would provide sub-regulatory guidance on them in the future, should there be a need for such guidance. We are proposing to eliminate the definition for "home health agency" because its definition is set out by statute at section 1861(o) of the Act. We propose to delete the term "progress notes" because notations in the clinical record and more typically referred to as "clinical notes," a term that is well defined and understood in the HHA industry.

We propose to delete the term "subunit" because the distinction between the requirements that the parent HHA and a subunit must meet are minor. Currently, a subunit must be able, independently, to meet the CoPs. The distinction between a "subunit" of a HHA and an independent HHA is that a "subunit" may share the same governing body, administrator, and group of professional personnel with its parent HHA. In practice, the requirement that a "subunit" must independently meet the CoPs renders this distinction

moot, and we believe that an entity operating for all intents and purposes as a distinct HHA should be treated as such. Therefore, upon finalization of this rule, existing subunits, which already operate under their own provider number, would be considered distinct HHAs and would be required to independently meet all CoPs without sharing a governing body or administrator. We propose to delete the requirements for the group of professional personnel; therefore it would no long matter if this group was shared among HHAs. Based on state-specific laws and regulations, this federal regulatory change would permit a subunit to apply to become a branch of its existing parent HHA if the parent provided "…direct support and administrative control" of the branch. The state survey agency and CMS Regional Office are responsible for approving a HHA's application for a branch office, in accordance with current CMS guidance as set out in various survey and certification letters and section 2182.4B of the State Operations Manual. No new subunits would be approved upon implementation of this regulation, only "branch offices."

Finally, we propose to add definitions for the terms "in advance," "quality indicator," "representative," "supervised practical training," and "verbal order." We would add a definition for the term "quality indicator" because the use of quality indicators is central to a HHA's successful implementation of a quality assessment and performance improvement program. HHAs already have numerous quality indicators available to them through the OASIS. The OASIS data set provides empirical data to measure the quality of care a Medicare patient receives from an HHA, including care delivery, patient outcomes, and potentially avoidable events. The data are able to demonstrate trends across time. The OASIS data and the measures calculated from that data are indicators of quality that can be

used for internal quality improvement efforts, in the survey process, and in the consumer decision-making process. However, the HHA quality indicators would not be limited to data gathered by the OASIS instrument or even measures calculated by CMS. HHAs may also identify quality indicators from outside sources such as research projects, collaborative QIO endeavors, and accrediting bodies, to name a few.

We propose to define the term "representative" in a patient-centered manner that enables patients to choose their representatives, if they wish to do so. We believe that the patient receiving services should be involved in the person-centered care planning process, and recognize that there are times when patients may want to involve other people in that process to assist in making decisions. Likewise, patients may also choose to designate another person to make all decisions on the patient's behalf. We believe that defining a "representative" in a manner that recognizes patient choice, both in who the representative is and in the role that the representative will play, would be beneficial to patients. We also propose to explicitly recognize legal guardians in situations where the patient has one. If a HHA has reason to believe that the representative is not acting in accordance with what the patient would want, is making decisions that could cause harm to the patient, or otherwise cannot perform the required functions of a representative, we would expect the HHA to make referrals and/or reports to the appropriate agencies and authorities to assure the health and safety of the patient.

We would define the term "verbal orders" to mean those physician orders that are delivered verbally (meaning spoken), by the physician, to a nurse or other qualified medical personnel, and recorded in the plan of care. "In advance" and "supervised practical

training" would be defined to provide clarity for clinical care purposes.

As discussed in detail in section III.D.4 of this preamble, we are proposing modifications to the current personnel qualifications requirements. Therefore, we would not retain the provisions of current §484.4, "Personnel qualifications," under proposed subpart A, General Provisions. These modifications would be set forth under proposed §484.80, "Home health aide services," and proposed §484.115, "Personnel qualifications."

We are also proposing to retain the current definitions of "primary home health agency," "public agency," and "summary report" without change.

C. Proposed Subpart B, Patient Care

1. Release of patient identifiable outcome and assessment information set (OASIS) information (Proposed §484.40)

At §484.40, we propose to recodify the current requirements of §484.11, which require an HHA and its agents to ensure the confidentiality of all patient-identifiable information in the clinical record, including the OASIS data.

2. Reporting OASIS information (Proposed §484.45)

In this CoP, we propose to include most of the current requirements of §484.20, which relate to the electronic reporting of the OASIS data. We propose to replace the current requirement that an HHA transmit data using electronic communications software that provides a direct telephone connection from the HHA to the state agency or CMS OASIS contractor. This requirement does not reflect current technology; therefore, we believe that it is no longer appropriate. Instead, we propose to add a requirement that the OASIS data be transmitted in accordance with current CMS transmission policy, which

currently requires HHAs to transmit data using electronic communications software that complies with the Federal Information Processing Standard (FIPS 140-2, issued May 25, 2001).

3. Patient rights (Proposed §484.50)

At §484.50, we propose to re-designate and modify the patient rights provisions that are found at current §484.10. Section 1891(a)(1) of the Act states a HHA must protect and promote the rights of each individual under its care. Currently, the patient rights provisions are organized into the following six standards: (1) Notice of rights; (2) Exercise of rights and respect for property and person; (3) Right to be informed and to participate in planning care and treatment; (4) Confidentiality of medical records; (5) Patient liability for payment; and (6) the Home Health hotline.

In this rule, we propose to reorganize patient rights under six standards: (1) Notice of rights; (2) Exercise of rights; (3) Rights of the patient; (4) Transfer and discharge; (5) Investigation of complaints; and (6) Accessibility. While the proposed patient rights provisions retain much of the basic focus of the current provisions, we believe our proposal presents a clearer and more organized view of our expectation of how HHAs should promote patient rights by focusing on ensuring patient safety and improving patient outcomes.

The current "Notice of rights" standard states only that the HHA must provide written notice of the patient's rights in advance of furnishing care, and that the HHA must maintain documentation demonstrating compliance. In proposed §484.50(a), we state that each patient and patient representative (if the patient has one), has the right to be informed

of his or her rights in a language and manner the individual understands. More specifically, under proposed §484.50(a)(1), we propose that the HHA provide the patient and patient's representative with verbal notice of the patient's rights in the primary or preferred language of the patient or representative, and in a manner that the individual can understand, during the initial evaluation visit, and in advance of care being furnished by the HHA. The patient's representative, who could be a family member or friend who accompanies the patient, may act as a liaison between the patient and the HHA to help the patient communicate, understand, remember, and cope with the interactions that take place during the visit, and explain any instructions to the patient that are delivered by the HHA staff. The representative would not need to be the patient's legal representative.

If a patient is unable to effectively communicate directly with HHA staff, then the HHA may effectively communicate patient rights information to the patient's representative. Communications with the representative would be required to be in the representative's primary or preferred language and in a manner that he or she can understand. Whether communicating with a patient or representative, HHA staff would be required to provide language assistance services or auxiliary aids and services at no cost, and provide notice of the availability of assistance, when necessary, to ensure effective communication between patients, representatives, and HHA staff. We note that the requirement to provide assistance and aids already exists as part of relevant statutes (for example, Title VI of the Civil Rights Act of 1964) and the regulations that implement these statutes (see 45 CFR parts 480, 405, and 490), and that HHAs agree to abide by these regulations as part of the provider agreement that they sign in order to participate in

Medicare (see 42 CFR part 489). Compliance with the existing statutes, regulations, and sub-regulatory guidance documents would satisfy the intent of this proposed provision.

If the patient or representative prefers using an interpreter of his or her own, he or she may do so. The HHA must ensure that the communication via the interpreter of choice is effective. HHAs may wish to document the offer and refusal of a professional interpreter in the patient's clinical record as evidence of compliance with the requirements of this section. A professional interpreter is not considered to be a patient's representative. Rather, it is the professional interpreter's role to pass information from the HHA to the patient.

We also propose to require that the patient be provided a written copy of the patient rights information. This could be provided in English or in the patient's primary or preferred language for present or future reference. The written information would be required to be provided in alternate formats free of charge for persons with disabilities, when necessary, to ensure effective communication. In addition, written notice would be required to be understandable to persons who have limited English proficiency. Furthermore, HHAs would be required to inform patients of the availability of the services and instruct patients how to access those services.

While we propose these requirements under the authority of sections 1861(o) and 1891 of the Act, Title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000d et seq.) and Section 504 of the Rehabilitation Act of 1973 also apply to HHAs, as well as other health care providers. Our proposed requirement has been designed to be compatible with guidance related to title VI of the Civil Rights Act of 1964. The Department of Health and

Human Services' (HHS) guidance related to Title VI, "Guidance to Federal Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons" (August 8, 2003, 68 FR 47311) applies to those entities that receive federal financial assistance from HHS, including HHAs that participate in Medicare and Medicaid. This guidance may assist HHAs in ensuring that patient rights information is provided in a language and manner the patient understands.

Proposed §484.50(a) (2) would require the HHA to provide each patient with specific business contact information for the HHA's administrator so that patients and caregivers could report complaints and specific patient rights violations to the HHA administrator, and so that patients and caregivers can ask questions about the care being provided.

We are also proposing at §484.50(a)(3) that the HHA provide a copy of the OASIS privacy notice to all patients from whom the OASIS data are collected at the same time that the general notice of rights is provided to the patient. The OASIS privacy notice would inform the patient why the OASIS information was being collected and describe the rights of the patient regarding the collection of this information. The OASIS privacy notice is available in English and Spanish, and can be found at http://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/OASIS/Regulations.html. Use of the OASIS Privacy Notice is required by the Federal Privacy Act of 1974, and must be used, in addition to other notices that may be required by other privacy laws and regulations. There is additional discussion of the use of the OASIS Privacy Notice in the Dec. 23, 2005 rule (70 FR 76199, 76201), where we

referred to a variety of provisions governing the privacy and security of the Federal automated information systems.

Finally, at §484.50(a)(4), we would require that the HHA obtain the patient's or representative's signature confirming that he or she has received a copy of the notice of rights and responsibilities.

The current standard at §484.10(b) sets out requirements for the exercise of patient rights and respect for property and person as one standard. We have stressed the importance of these two individual concepts by proposing to separate the requirements into 2 standards at §484.50(b), "Exercise of rights" and at §484.50(c), "Rights of the patient." Under proposed §484.50(b), in the event that a patient was declared incompetent under state law by a court of proper jurisdiction, the rights of that patient could be exercised by the person appointed by the state Court. If a state court had not made a declaration, any representative, as chosen by the patient, could exercise the rights of the patient in accordance with the patient's preferences. In situations where a patient has been adjudged to lack legal capacity under state law by a court of proper jurisdiction, the patient would be allowed to exercise his or her rights to the extent allowed by the court order. We propose these provisions in recognition of the complexities of representation. There are many circumstances under which representatives may be used, and the extent of such representation varies from one patient to another. Some patients may require total representation because they are unable to communicate and advocate for themselves. Others may be able to participate in their care to a certain degree and require representation as a supportive mechanism. Still other patients may wish to hand off decision-making and

advocacy responsibilities to another person even though these patients are fully capable of fulfilling this role themselves. Our goal is to provide guidance to HHAs regarding how to address these situations and intricacies in the most patient-centered, patient-directed way possible. We specifically seek public comment on ways to assure that patient choice is respected and upheld, while also balancing the need to assure patient safety.

Proposed §484.50(c) would set forth the explicit rights of each home health patient. At §484.50(c) (1), we propose that the patient would have a right to have his or her property and person treated with respect. At §484.50(c) (2), we propose that the patient would have a right to be free from verbal, mental, sexual and physical abuse, including injuries of unknown source, neglect, and misappropriation of property. If an injury of unknown source is identified, we would expect the HHA to investigate the injury in order to determine its cause and take action to prevent further injuries related to that source. Under proposed §484.50(c)(3), the patient would have a right to make complaints to the HHA regarding treatment or care that was (or failed to be) furnished which the patient and/or their family believe was inappropriate. Under proposed §484.50(c)(4), patients and their representatives would also have the right to participate in, be informed about, and consent or refuse care. Moreover, each patient would have the right to participate in and be informed about the patient-specific comprehensive assessment, including an assessment of the patient's goals and care preferences. We expect that this assessment would focus on goals and preferences that are specific to the delivery of home health care. Additionally, each patient would have the right to participate in and be informed about the care that the HHA will furnish based on the needs identified during the comprehensive assessment,

establishing and revising that plan, the disciplines that will furnish care, the frequency of visits, identifying expected outcomes of care, and any factors that could impact treatment effectiveness. In accordance with proposed §484.50(c)(4)(iii), each patient would also have the right to receive a copy of his or her individualized HHA plan of care to be kept in his or her home, including all updated plans of care, as described in proposed §484.60. HHAs would be required at §484.50(c)(4)(viii) to inform the patient about any changes in the care to be furnished in advance of those changes being made in the patient's plan of care. In addition to being involved in the care planning process, we would add a requirement at §484.50(c)(5) that patients have the right to receive all of the services outlined in the plan of care. Additionally, we propose to retain the current requirements from current §484.10(d), which concern the patient's right to the confidentiality of his or her clinical records, under proposed §484.50(c)(6). In order to maintain confidentiality within the patient's home, as we are proposing at §484.50(c)(4)(iii), we would expect an HHA to educate a patient and family about how to store the copy of the patient's plan of care in the patient's home.

Proposed §484.50(c)(7), would retain the requirements of the current standard at §484.10(e), Patient liability for payment. Patients would be informed about which services would be covered, which services might or might not be covered, and the patient's liability for payment. This patient liability requirement would be related to the home health advance beneficiary notice (ABN) and home health change of care notices; therefore, we propose to reference the current requirements at §411.408(d)(2) and §411.408(f). HHAs would be required to comply with all ABN requirements, including restrictions related to

who may receive the ABN on the patient's behalf.

In accordance with the requirements of the Medicare provider agreement, HHAs must not discriminate against Medicare beneficiaries, and if a participating HHA accepts non-Medicare patients at any given level of acuity, it must also accept Medicare beneficiaries at a similar level of acuity as a condition of participating in the Medicare program. HHAs that provide services to non-Medicare patients while refusing services to Medicare patients in similar situations risk having their provider agreements terminated, in accordance with §489.53(a)(2).

At proposed §484.50(c)(8), we would retain the basic concept of the requirement at current §484.10(e) regarding patient payment liabilities. A patient would have the right to receive proper written notice, in advance of a specific service being furnished, if the HHA believes that the service may be non-covered care; or in advance of the HHA reducing or terminating on-going care. We propose to revise this current requirement by cross-referencing the regulations regarding expedited reviews, found at 42 CFR part 405, subpart J. These requirements protect patients from unexpected bills for usually covered care, which may not be covered by Medicare in a particular instance, and ensures patient access to the expedited review process.

We would retain the current standard found at §484.10(f), regarding the home health hotline at proposed §484.50(c)(9). The home health hotline provides an important avenue for patients to register complaints against, or pose questions about, an HHA. Patients would still retain the right to be informed of the availability of the toll-free home health hotline in their state, including the telephone number and the hours of operation.

The patients would be advised that the purpose of the hotline was to receive complaints or questions about local HHAs. Additionally, under §484.50(c)(10), patients would be advised of the names, addresses, and telephone numbers for relevant Federally and State-funded consumer information, consumer protection, and advocacy agencies. HHAs should select agencies that have a public service mission and provide assistance free of charge, such as area Agencies on Aging, Aging and Disability Resource Centers, legal service programs, State Health Insurance Programs, and Adult Protective Services. HHAs would have the discretion to select, for inclusion in the list, those local agencies and organizations that are likely to be most appropriate for the needs of each HHA's unique patient population.

We also propose at §484.50(c)(11), that patients have the right to be free from discrimination or reprisal for exercising their rights, whether by voicing grievances to the HHA or to an outside entity, such as those advocacy and protection agencies described above. Examples of discrimination or reprisal may include a reduction of current services or a complete discontinuation of services and discharge from the HHA.

Finally, we propose at §484.50(c)(12) that patients have the right to be informed of their right to access auxiliary aids and language services, and to be provided instruction on how to access these services. We believe that making auxiliary aids and language services available to patients, to facilitate an understanding of their rights and to facilitate the provision of care throughout the care planning and care delivery process will improve the quality and effectiveness of the care that is delivered, and will improve the patient's experience of care as a whole.

We propose to add a new standard at §484.50(d), which would mandate that all patients and representatives (if any), have the right to be informed of the HHA's policies governing admission, transfer, and discharge. This proposed standard would list the criteria by which an HHA could discharge or transfer a patient. The proposed criteria are designed to help prevent the untimely discharge of home health patients and ensure that patients are discharged or transferred only under appropriate circumstances. This proposed standard would require that the HHA inform its patients of its policies governing admission, transfer, and discharge in advance of the HHA providing care. Under this proposed standard, an HHA could only transfer, discharge, or terminate care for the following reasons: (1) when the HHA could no longer meet the patient's needs, based on the patient's acuity; (2) when the patient or payer could no longer pay for the services provided by the HHA; (3) when the physician and HHA agreed that the patient no longer needed HHA services because the patient's health and safety had improved or stabilized sufficiently; (4) when the patient refused HHA services or otherwise elected to be transferred or discharged (including if the patient elected the Medicare hospice benefit); (5) when there was cause; (6) when a patient died; or (7) when the HHA ceased to operate.

In accordance with the requirements of proposed §484.50(d)(1), if the care needs of a patient exceeded the HHA's ability to provide services, the HHA would be required to ensure that the patient received a safe and appropriate transfer to another care entity better suited to meeting the patient's needs. There are no regulations in the current CoPs that address these issues. However, this provision is consistent with the decision in *Lutwin v. Thompson* 361 F.3d 146 (2nd Cir. 2004) regarding the provision of notice when services are

reduced or terminated.

Likewise, although current CMS guidance (Pub. 100-02, Chapter 7, Section 10.10, Discharge Issues) allows discharge for cause, there are no regulations in the current CoPs that address these issues. We are proposing to add §484.50(d)(5) to permit discharge for cause if the patient's (or other persons in the patient's home) behavior is so disruptive, abusive, or uncooperative that the delivery of care to the patient or the ability of the HHA to operate effectively and safely is seriously impaired. Before discharging a patient for cause, the HHA would be required to advise the patient, the representative (if any), the physician who is responsible for the home health plan of care, and the patient's primary care practitioner or other health care professional who will be responsible for providing care and services to the patient after discharge from the HHA (if any) that a discharge for cause was being considered, make efforts to resolve the problem(s) presented by the patient's behavior or by other person(s) in the home (as applicable), or situation (such as a dangerous animal being loose in the home), document the problem(s) and efforts made to resolve the problem(s), and enter this documentation into its clinical records. Additionally, we propose that the HHA would be required to provide the patient and representative (if any), with contact information for other agencies or providers who may be able to provide care following the discharge. It would be incumbent upon the HHA to take all reasonable steps to resolve safety and noncompliance issues prior to taking steps to discharge a patient.

Given the vulnerability of home health patients and in the interest of patient safety, we propose a standard at §484.50(e), "Investigation of complaints," that would expand upon the current complaint investigation requirements at §484.10(b)(5). Proposed

§484.50(e)(1)(i) would require the HHA to investigate complaints made by patients, representatives, caregivers, and families regarding treatment or care that is (or fails to be) furnished, is furnished inconsistently, or is furnished inappropriately. In addition, HHAs would be required to investigate allegations of mistreatment, neglect, or verbal, mental, psychosocial, sexual, and physical abuse, including injuries of unknown source, and/or misappropriation of patient property by anyone furnishing services on behalf of the HHA. This requirement would clarify that all patient complaints should be investigated by HHAs. Proposed §484.50(e)(1)(ii) would require the HHA to document both the existence and the resolution of the complaint, while §484.50(e)(1)(iii) would require the HHA to take immediate action to prevent further potential abuse while the complaint was being investigated. We believe that HHAs should be permitted the flexibility to establish their own policies and procedures for documenting and resolving complaints, and we would expect HHAs to consistently adhere to these policies and procedures.

Proposed §484.50(e)(2) would require any HHA staff, regardless of whether they are employed directly or obtained under arrangements with another entity, to immediately report to the HHA administrator or other appropriate authorities any incidences of mistreatment, neglect, or abuse, and/or any misappropriation of patient property, which they have noticed during the normal course of providing services to patients. Since HHA staff is in a unique position to recognize signs of patient abuse in the home, this proposed requirement would serve to further ensure the health and safety of home health patients. "Appropriate authorities" may include, but are not limited to, state and local law enforcement, health care ombudsmen, and State survey agencies.

To address effective communication with patients who are LEP or have disabilities, we are proposing a new standard at §484.50(f), "Accessibility." We propose that information that is provided to patients would be provided in plain language, and in a manner that is both accessible and timely to the individual. For people with disabilities, providing access includes the use of accessible websites and the provision of auxiliary aids and services, such as qualified interpreters and alternate formats. For persons with LEP, providing access includes providing oral interpretation and written translations.

4. Comprehensive assessment of patients (Proposed §484.55)

We propose to retain the majority of the substantive requirements of current §484.55, with significant reorganization. We propose to retain the requirement that each patient be required to receive a patient-specific comprehensive assessment. We also propose to retain the requirement that, for Medicare beneficiaries, the HHA would be required to verify the patient's eligibility for the Medicare home health benefit, including the patient's homebound status, at the specified timeframes. Furthermore, we propose to retain all requirements related to the initial assessment visit at standard (a), as well as the completion of the comprehensive assessment requirements at standard (b).

We propose to establish a new standard (c), "Content of the comprehensive assessment," that would incorporate much of the content currently set forth in the introductory paragraph of the CoP, the drug regimen review currently set forth in standard (c), and the incorporation of the OASIS data items requirement currently set forth at standard (e). We also propose new content requirements, such as an assessment of psychosocial and cognitive status, which we believe would provide for a more holistic

patient assessment. We propose to require that the comprehensive assessment must accurately reflect the patient's status, and would assess or identify (as applicable) the following:

- The patient's current health, psychosocial, functional, and cognitive status;
- The patient's strengths, goals, and care preferences, including the patient's progress toward achievement of the goals identified by the patient and the measurable outcomes identified by the HHA;
- The patient's continuing need for home care;
- The patient's medical, nursing, rehabilitative, social, and discharge planning needs;
- A review of all medications the patient is currently using;
- The patient's primary caregiver(s), if any, and other available supports; and
- The patient's representative (if any).

The assessment would also be required to incorporate items from the information collection set out in the OASIS data set, using the language and groupings of the OASIS items, as specified by the Secretary.

We propose to retain the majority of the content of the requirements of current §484.55(d), with one change. Currently §418.55(d)(2) generally requires that an update of the comprehensive assessment must be completed within 48 hours of a patient returning home after a hospital admission. This fixed requirement does not allow ordering physicians to modify the time frame for the HHA to resume its care. We believe that it is in the best interest of patients to allow for more physician discretion so that physicians can tailor the resumption of home health care to the specific needs of a patient. Therefore, we

propose to revise §484.55(d)(2) to allow for a physician-ordered resumption of care date as an alternative to the fixed 48 hour time frame.

5. Care planning, coordination of services, and quality of care (Proposed §484.60)

Current regulations concerning the plan of care are set forth at §484.18, "Acceptance of patients, plan of care, and medical supervision." We propose to revise that requirement, as well as current §484.14(g), "Coordination of patient services," by creating a new condition of participation, "Care planning, coordination of services, and quality of care" at §484.60. This section would specify that the HHA would have to provide the patient a plan of care that would set out the care and services necessary to meet the patient-specific needs identified in the comprehensive assessment, and the outcomes that the HHA anticipates would occur as a result of developing the individualized plan of care and subsequently implementing its elements. We propose five standards under this CoP, which we believe reflect and encourage the interdisciplinary approach to home health care delivery. We would reorganize the current standards to place the events in the care planning process in sequential order: (1) plan of care at §484.60(a); (2) conformance with physician orders at §484.60(b); (3) review and revision of the plan of care at §484.60(c); (4) coordination of care at §484.60(d); and (5) discharge or transfer summary at §484.60(e).

In this CoP, we propose to require that patients be accepted for treatment on the basis of a reasonable expectation that the patient's medical, nursing, rehabilitative, and social needs could be met adequately by the agency in the patient's place of residence. Each patient would receive an individualized written plan of care which would specify the

care and services necessary to meet the patient's needs, including the patient and caregiver education and training that the HHA will provide, specific to the patient's care needs. A copy of this individualized plan would be provided to each patient and representative (if any), in accordance with the proposed patient rights requirements at §484.50(c)(4)(iii). We believe that providing each patient with a copy of his or her plan of care will improve HHA-patient communications and enable patients to more thoroughly understand the care that they are to receive. We also believe that part of providing this information is teaching patients and their families how to protect the information in order to ensure their right to a confidential record, as would be required in proposed §484.50(c)(6). The individualized plan of care would be revised or added to at intervals as necessary to continue to meet patient care needs.

We also propose that the plan of care include the patient-specific measurable outcomes which the HHA anticipates would result from its implementation. As described in proposed §484.50(c)(4), the patient has the right to participate in his or her care planning, including the establishment of goals and outcomes of care. We would expect the plan of care to be reflective of the improvement, maintenance, and/or prevention goals and outcomes specific to each patient's condition. As noted in a recent update to the Medicare Benefit Policy Manual (CR 8458, http://www.cms.gov/Regulations-and-Guidance/Guidance/Transmittals/Downloads/R179BP.pdf), consistent with the settlement agreement in the case of Jimmo v. Sebelius, maintenance of the patient's current condition and prevention or slowing of further deterioration of the patient's condition may both warrant the use of skilled care provided under the Medicare home health benefit. All

services furnished by the HHA for all purposes would be provided in accordance with accepted standards of practice.

Under proposed §484.60(a)(1), Plan of care, we propose that all home health services furnished to patients would follow an individualized written plan of care, setting out, among other things, the frequency and duration of therapeutic interventions. The plan would be established, periodically reviewed, and signed by a doctor of medicine, osteopathy, or podiatric medicine acting within the boundaries of all applicable state laws and regulations. An evidence and outcome-based approach to patient care that can be understood by the patient and caregivers, with specificity of orders and adherence to best practice interventions, would provide a basis for the development of the optimal plan of care and goals. Patients participating in the shared decision-making model, where there is a mutually respectful exchange that recognizes the individuality of the patient and a process in which responsibility is divided among the patient, physician, and agency acting on physician orders, will better understand the goals of treatment. These patients are more likely to actively participate in the treatment process and achieve better treatment outcomes. ("A typology of preferences for participation in healthcare decision making," http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=1637042) The shared decision making model has been embraced in literature ("Decision-making in the physician–patient encounter: revisiting the shared treatment decision-making model", http://www.sciencedirect.com/science/article/pii/S0277953699001458; "Four Models of the Physician-Patient Relationship," JAMA (1992). ; "Physician Recommendations and Patient Autonomy: Finding a Balance between Physician Power and Patient Choice,"

http://annals.org/article.aspx?articleid=710110), and the Institute of Medicine has recommended including it in medical school curricula as a mechanism to improve care (Institute of Medicine, "Improving Medical Education: Enhancing the Behavioral and Social Science Content of Medical School Curricula" (2004)) (See also brown.edu/.../Mod2SharedDecMaking/Teachingmats/Handout1SDMDefined.doc). This standard would require that each patient's home health services be furnished under a written, patient-specific plan of care that would identify patient-specific measurable outcomes and goals selected jointly by the HHA and the patient.

We are soliciting public comments regarding methods to engage patients and the physicians who are responsible for their plans of care in the care planning and management process. Specifically, we are interested in ways to maximize the level of involvement of the physician who is most involved in the patient's care prior to admission to the home health agency, and who is responsible for overall treatment of the condition(s) that led to the need for home health care. We believe that the continual involvement of physicians may facilitate better transitions of care, improve patient outcomes, and reduce acute care admissions by clearly establishing (and updating) treatment goals and plans, and effectively delivering care that meets those goals. We are also interested in ways to facilitate communication between the HHA and other physicians and practitioners (such as nurse practitioners and physician assistants) who may be furnishing care for issues that are not directly connected to the issues being addressed by the HHA. Additionally, we are interested in ways to facilitate communication with those physicians and practitioners who will be responsible for managing the patient's care after the patient is discharged from the

HHA. We believe that actively soliciting input from these clinicians may help improve the transitions into and out of home health care.

The individualized plan of care would be required to include all pertinent diagnoses; the patient's mental, psychosocial, and cognitive status; the types of services, supplies, and equipment required; the frequency and duration of visits to be made; prognosis; rehabilitation potential; functional limitations; activities permitted; nutritional requirements; all medications and treatments; safety measures to protect against injury; patient and caregiver education and training to facilitate timely discharge or referral; patient-specific measurable outcomes/goals; and any additional interventions/orders the HHA or physician chose to include. We note that it is important for HHAs to consider the social determinants that may contribute to poor health outcomes, as many current approaches to prevention, treatment, and disease control are limited to an individual's diagnosis and related risk factors. There is often a lack of awareness and/or assessment of the factors that may enhance or create a barrier to good health outcomes. Factors such as low income, lack of access to a primary care practitioner, poor nutrition due either to poor choices and/or lack of availability of healthy and affordable food items (for example, "food deserts"), and other environmental, social, and/or emotional issues may affect compliance and/or adherence with medical care and treatment. The HHA staff must be aware of the social and/or economic circumstances in which people are born, grow up, live, work, and age, as well as what are in place for their overall health care. This contributes to the HHAs ability to identify state, local, and/or federal resources the patient may need in order to design a holistic plan of care that may result in improved health outcomes, care, and

treatment results. For example, if an elderly, low income, insulin dependent diabetic patient is not able to afford regular meals, the home health agency staff may refer to local resources such as a food bank, meals on wheels, or other resource. Diabetic patients must have regular meals for blood sugar control. Lack of awareness and intervention related to this factor may result in a poor outcome for the patient. The Underserved Populations (UP) Network provides resources, tools, and webinars for agencies via http://www.homehealthquality.org/UP.aspx focused on improving outcomes.

In order to implement the individualized physician-prescribed plan of care, agencies often develop a discipline-oriented plan, wherein each specific service being provided (for example, physical therapy, occupational therapy, and speech-language pathology) sets out findings, treatment goals, and interventions planned in order to achieve those goals in compliance with the physician's orders.

If HHA services are initiated following a patient's hospital discharge, we propose to require that the HHA must include an assessment of the patient's level of risk for hospital emergency department visits and hospital re-admission. In order to establish the patient's risk level, we believe that HHAs would identify the patient's specific risk factors. We propose that HHAs would be required to include in the patient's individualized plan of care all appropriate interventions that are necessary to address and mitigate those identified risk factors that contribute to the HHA's establishment of a particular risk level for a patient. Resources to assist HHAs in assessing re-hospitalization risks are available at http://www.homehealthquality.org.

Proposed §484.60(b), "Conformance with physician orders," would provide that

drugs, services, and treatments be administered only as ordered by the physician who is responsible for the home health plan of care, a requirement that is currently set forth at §484.18(c). This proposed standard also would reflect the vaccination policies of the final rule with comment period published in the **Federal Register** on October 2, 2002 (67 FR 61808), also set forth at §484.18(c). That rule provided an exception from the physician order requirement for the administration of influenza and pneumococcal polysaccharide vaccines. The current requirement allows influenza and pneumococcal polysaccharide vaccines to be administered based on a HHA policy developed in consultation with a physician, and after an assessment for contraindications. We propose to retain this requirement at §484.60(b)(2). Proposed §484.60(b)(4) would maintain the requirement that only personnel authorized by applicable state laws and regulations and the HHA's internal policies, may accept verbal orders from physicians. We would maintain the intent of the current requirement at §484.18(c) by proposing at §484.60(b)(5) that a registered nurse (RN) or other qualified practitioner who is licensed to practice by the state must document the order in writing in the patient's clinical record, with a signature, time, and date. As described in the definitions section, for purposes of this rule, verbal orders are those physician orders that are spoken to qualified medical personnel. Verbal orders would also have to be recorded in the patient's plan of care. Reliance on a HHA to maintain physician orders in written form would protect patients by ensuring that the plan of care incorporated all services and treatments ordered by the physician who is responsible for the home health plan of care. If a physician faxed orders or otherwise transmitted them through other electronic methods from his or her office, those orders would be required to

be included in the patient's clinical record and plan of care. The proposed rule would provide an opportunity for an HHA to establish policies defining who is authorized to accept physicians' verbal orders. The categories of practitioners identified as being authorized to accept physicians' verbal orders by the HHA would be required to be consistent with state requirements.

We would also require, under proposed §484.60(b)(5), that verbal orders be authenticated, dated, and timed by the physician according to the HHA's internal policies and applicable state laws and regulations. Many states in their licensure requirements, and HHAs in their policies, have established timeframes for physician countersignature of verbal orders in accordance with the agency's risk tolerance, legal liability, and logistical concerns. Although timeframes may vary, we support state requirements and HHA flexibility in this regard, and do not propose a separate timeframe requirement for physician countersignature for verbal orders for HHA providers. In addition to all applicable state requirements and agency policies, HHAs should also be aware of CMS payment reimbursement requirements, which state that a final claim for each episode of care may not be submitted until all orders are signed.

Under proposed §484.60(c), "Review and revision of the plan of care," we propose that the individualized plan of care be reviewed and revised by the physician who is responsible for the HHA plan of care and the HHA as frequently as the patient's condition or needs requires, but no less frequently than once every 60 days, beginning with the start of care date. While the provision would require review and revision at least every 60 days, we expect that physicians and agency staff would communicate more frequently if a

patient's condition warranted it. To ensure patient health and safety, we propose that the HHA promptly alert the physician who is responsible for the HHA plan of care to any changes in the patient's condition or needs that would suggest that measurable outcomes are not being achieved and/or that the HHA should alter the plan. At §484.60(c)(2), we propose to require that the HHA revise the plan of care, as necessary, to reflect current information from the patient's updated comprehensive assessment, and to record the patient's progress towards meeting the patient-specific measurable outcomes and goals selected by the HHA and patient, as specified in the plan of care. It would be the HHA's responsibility to make certain that all aspects of the revised plan of care were implemented.

Furthermore, we propose that it would be the HHA's responsibility to notify the patient, representative (if any), caregivers, and the physician who is responsible for the HHA plan of care, when the individualized plan of care is updated due to a significant change in the patient's health status. We also propose that, when the HHA makes updates related to plans for the patient's discharge, the HHA would communicate these changes with the patient and representative, caregivers, the physician who is responsible for the HHA plan of care, and the patient's primary care practitioner or other health care professional who will be responsible for providing care and services (if any) to the patient after discharge from the HHA. We believe that communicating with the patient and those who will be continuing to furnish services to the patient after home health services are discontinued regarding changes related to plans for discharge prior to the discharge would allow time for important discussions, preparations, and coordination activities. We note that the patient's primary care practitioner or other health care professional who will be

responsible for providing care and services to the patient after discharge from the HHA may be a specialist, a nurse practitioner, a physician assistant, or another type of medical service. In proposed §484.60(d), "Coordination of care," we propose to require that the HHA must integrate services, whether services are provided directly or under arrangement, to assure the identification of patient needs and factors that could affect patient safety and treatment effectiveness, the coordination of care provided by all disciplines, and communication with the physician. The proposed standard at §484.60(d)(2) would also require the HHA to coordinate care delivery to meet each patient's needs, and to involve the patient, representative (if any), and caregiver(s), as appropriate, in the coordination of care activities. It is our goal to support and foster collaboration and communication among the professional disciplines responsible for caring for a patient. It would be the agency's responsibility to determine the degree of coordination necessary to meet the needs of the patient, and to develop an approach that best implemented the coordination of the patient's care. It would also be the agency's responsibility to determine the most appropriate and effective way to provide evidence during a survey that these care coordination activities were occurring on a continual basis for every patient, and that the agency was assessing the impact of care coordination activities on patient care utilizing the HHA's quality assessment and performance improvement program, if appropriate.

Finally, under proposed §484.60(d)(3), we propose that the HHA ensure that each patient and caregiver, where applicable, receive ongoing training and education from the HHA regarding the care and services identified in the plan of care that the patient and caregiver are expected to implement. This proposed requirement is consistent with those in

the current payment-related regulations at §409.42(c)(1). Ongoing patient training and education includes all periods of time that the patient is receiving care from an HHA, from admission through the day of discharge. The training would include educating the patient about his or her post HHA discharge care duties and the need (as appropriate) to follow-up with the patient's primary care practitioner or other health care professional who will be responsible for providing care and services to the patient after discharge from the HHA. The HHA would be required to ensure that each patient and caregiver receives any training necessary to achieve the patient-specific measurable outcomes outlined in the plan of care, which are necessary for a timely discharge from the HHA. Each skilled professional would be expected to be responsible for educating the patient and/or caregiver about the care and services as appropriate to the discipline.

Under Medicare's home health benefit, when applicable, HHAs are expected to provide education and training to their patients. For instance, HHAs are expected to provide education and training to help insulin dependent diabetes mellitus (IDDM) patients and other diabetic patients self-manage their diabetes. Many homebound patients with diabetes require short-term management for skilled observation, assessment, teaching, and training activities. If the patient is unable to learn to self-manage, including self-administer medication, the HHA would be expected to provide the teaching and training to a care-giver or family member. We also encourage HHAs to take advantage of the help and support available from organizations that teach innovative techniques associated with diabetes self-management training (DSMT). Collaborating with these organizations may allow HHAs to achieve greater success in enabling patients and/or their caregivers to better

achieve self-management, and may provide the HHAs with innovative care suggestions regarding their patients.

At §484.60(e), Discharge or transfer summary, we propose that HHAs would compile a discharge or transfer summary for each discharged or transferred patient. The summary would be required to include the following:

- The initial reason for referral to the HHA,
- A brief description of the patient's HHA care,
- A description of the patient's clinical, mental, psychosocial, cognitive, and functional status at the start of care,
- A list of all services provided by the HHA to the patient,
- The start and end dates of HHA care,
- A description of the patient's clinical, mental, psychosocial, cognitive, and functional status at the end of care,
- The patient's most recent drug profile,
- Any recommendations for follow-up care,
- The patient's current individualized plan of care, and
- Any additional documentation that will assist in post-discharge or transfer continuity of care, or that is requested by the receiving practitioner or facility.

We propose to include these elements in the discharge or transfer summary to provide the clear and comprehensive summary that is necessary for effective and efficient

follow-up care planning and implementation as the patient transitions from HHA services to another appropriate health care setting.

6. Quality assessment and performance improvement (QAPI) (Proposed §484.65)

Beginning with the 1999 Institute of Medicine (IOM) report entitled "To Err is Human: Building a Safer Health System," the focus in health care changed from an incident-based, after-the-fact quality improvement focus to a pre-emptive, proactive quality assessment and performance improvement focus. CMS evaluated and responded to the recommendations in the IOM report through a coordinated effort called, "Doing What Counts for Patient Safety: Federal Actions to Reduce Medical Errors and Their Impact." As part of our effort to reduce medical errors, and improve the quality of health care in all settings, we propose to replace two current HHA CoPs, §484.16, "Group of professional personnel," and §484.52, "Evaluation of the agency's program," with a single, new CoP, at §484.65, "Quality Assessment and Performance Improvement" (QAPI). Overall, this proposed QAPI CoP is consistent with the QAPI program requirements for end stage renal disease facilities (§494.110), hospitals (§482.21), hospices (§418.58), organ procurement organizations (§486.348), and transplant centers (§482.96).

We believe that the proposed QAPI CoP would provide an opportunity for HHAs to develop a program that would enable them to identify areas for improvement which would help to ensure quality care and patient safety. In addition, we are emphasizing that the HHA would be required to take actions to prevent and reduce medical errors as part of their overall QAPI program. We have organized this new CoP into the following five standards: (1) Program scope; (2) Program data; (3) Program activities; (4) Performance improvement

projects; and (5) Executive responsibilities.

The current CoPs rely on a problem-oriented, external, after the fact (occurrence) approach to resolve patient care issues. The proposed QAPI CoP would require proactive performance monitoring through an effective, ongoing, agency-wide, data-driven QAPI program that is under the supervision of the home health agency governing body.

In proposed §484.65(a), "Program scope," we propose that this data-driven QAPI program would be capable of showing measurable improvement in indicators for which there was evidence that the improvement led to improved health outcomes (for example, reduced hospitalizations and readmissions), safety, and quality of care for patients. The HHA would also have to measure, analyze, and track quality indicators, including adverse patient events, as well as other indicators of performance so that the agency could adequately assess its processes, services, and operations.

We propose, at §484.65(b), "Program data," that a HHA's QAPI program utilize quality indicator data, including measures derived from the OASIS (CMS provided reports), where applicable, and other relevant data, to assess the quality of care provided to patients, and identify and prioritize opportunities for improvement. Quality assessment efforts, including data collection, should focus on high priority safety and health conditions, and other goals identified by a HHA. The tools, collected data, and associated quality measures would be used by the HHA to monitor the effectiveness and safety of its services, as well as the quality of its care. In addition, the HHA would use the quality measures that are calculated based on the data collected to identify opportunities for improvement. We also propose that the HHA's governing body would be responsible for

approving the frequency of, and level of detail to be used in data collection. This level of flexibility would allow HHAs to establish data collection and analysis policies and procedures that reflect currently accepted standards and practices.

At §484.65(c), Program Activities, we would require a HHA's QAPI program activities to focus on high risk, high volume, or problem-prone areas of service, and to consider the incidence, prevalence, and severity of problems in those areas. We also propose that the HHA immediately correct any identified problems that directly or potentially threaten the health and safety of patients. Additionally, the HHA's QAPI activities would have to track incidents and adverse patient events, as well as analyze those events, so that preventive actions and mechanisms could be implemented by the HHA. We also propose that after steps have been taken to improve an area of concern, the HHA would continue to monitor the area in order to assure that improvements were sustained over time.

Proposed §484.65(d), Performance improvement projects, would require that the HHA's performance improvement projects, conducted at least annually, reflect the scope, complexity, and past performance of the HHA's services and operations. An agency would need to focus on those areas of past performance which have proven to be problematic for the HHA over time or areas where there was clear evidence of poor patient outcomes, as well as areas of high-risk and high-volume. High-risk and high-volume areas will vary based on a HHA's patient population and other unique characteristics. For example, wound care could be a high-risk area for a HHA because the HHA does not perform the care very often, and thus may not be up-to-date on the latest techniques. Likewise, wound care could

be a high-volume area for another HHA with a large number of patients requiring wound care services, increasing the likelihood of a problem occurring due to the sheer number of wound care visits that would occur. Data gathered either through the OASIS data set or through other measurement data collection tools, and subsequent analysis of the data, would be used to identify these areas. Within this standard, we also propose that the HHA document the QAPI projects undertaken, the reasons for conducting these projects, and the measurable progress achieved.

Finally, under proposed §484.65(e), "Executive responsibilities," we would require that the HHA's governing body assume responsibility for the agency's QAPI program. This subsection would require that the governing body assume the overall responsibility for ensuring that the QAPI program reflected the complexity of the HHA and its services, involved all services (including those provided under contract or arrangement), focused on indicators related to improved outcomes, and took actions that addressed the HHA's performance across the spectrum of care, including the prevention and reduction of medical errors. In the opening paragraph of §484.65 we also propose to require the HHA to maintain documentary evidence of its QAPI program and to demonstrate its operation to CMS during the survey process.

The governing body would be required to define, implement, and maintain a program for quality improvement and patient safety that was ongoing and agency-wide. The governing body would be required not only to ensure that performance improvement efforts were prioritized, but that they were also evaluated for effectiveness. We note that it is the governing body which would be ultimately responsible for establishing the HHA's

expectations for patient safety through an agency-wide QAPI program. Therefore, we propose that the governing body establish clear expectations for patient safety. We also propose that the governing body would appropriately address any findings of fraud or waste in order to assure that resources are appropriately used for patient care activities and that patients are receiving the right care to meet their needs.

We believe small and mid-size HHAs would be able to effectively implement this condition as easily as larger HHAs. The proposed QAPI CoP would provide HHAs with enough flexibility to implement the quality assessment and performance improvement process without inordinate expenditure of capital or human resources. An HHA could also use outside resources to assist in development and support of its QAPI program. Each HHA's QAPI program should be individualized to reflect the size, scope, and complexity of its services and patient population. Therefore, we do not believe there is a need to differentiate our expectations for QAPI between small-to-mid-size HHAs and larger HHAs.

We have also chosen not to be prescriptive in this requirement because every HHA is different, and mandating "a one-size-fits-all," process-oriented quality assessment and performance improvement program would not be beneficial to the patients or the HHA. Each HHA would be expected to conduct its QAPI program in a way that best meets its needs and the needs of that HHA's patients. HHAs would be able to utilize data from the OASIS data set through the risk-adjusted outcome-based quality improvement (OBQI), outcome-based quality management (OBQM), and process based quality improvement (PBQI) reports. Case-mix-adjusted outcome reports give agencies a "snapshot" of their individual agency's performance. The OASIS data set provides much of the necessary data

items for CMS and HHAs to measure outcomes, potentially avoidable events, and patient/agency risk adjustment factors and for CMS to generate OBQI, OBQM, and PBQI reports. (The Outcome-Based Quality Improvement（OBQI) Manual (September 2002) and CASPER Reporting Application are located in the download section of CMS' HHQI OASIS OBQI web page at http://www.cms.gov/HomeHealthQualityInits/16_HHQIOASISOBQI.asp#TopOfPage and http://www.cms.gov/HomeHealthQualityInits/18_HHQIOASISOBQM.asp#TopOfPage. The PBQI Manual (May 2010) is located in the "downloads" section of CMS'OASIS PBQI / Process Measures web page section at http://www.cms.gov/HomeHealthQualityInits/15_PBQIProcessMeasures.asp#TopOfPage). The OBQI, OBQM, and PBQI reports can be used to assess the quality of care at HHAs and provide information to assist them in ongoing quality improvement.

In addition to these resources, there are other existing resources already in place through http://www.homehealthquality.org that support issues addressed in this proposed CoP. The Home Health Quality Initiative (HHQI) is part of the Quality Improvement Organization program established by CMS. Established in 2007, its goal is to improve the quality of home care services patients receive as measured by improvement in selected publicly reported and other clinical measures. Participation in the HHQI is free to all Medicare-participating HHAs. Participating HHAs have access to many resources that may aide in their QAPI efforts, such as best practice intervention packages that offer practical applications of quality improvement strategies to improve performance, individualized data reports via a secure online portal to assist with measuring progress,

networking and educational opportunities via webinars scheduled at least monthly, and prompt assistance to address needs and questions. In particular, the HHQI provides resources related to falls prevention, flu and pneumonia vaccinations, oral medication management, and patient self-management.

Through the survey process, we intend to assess whether HHAs have all of the components of a QAPI program in place. Surveyors would expect HHAs to demonstrate, with the objective data from the OASIS data set and other sources available to the HHA, that improvements had taken place with respect to actual care outcomes, processes of care, patient satisfaction levels and/or other quality indicators. Additionally, surveyors would expect the HHA to demonstrate that all disciplines are involved in its QAPI program, consistent with the requirements of proposed §484.75(c), below.

We believe that physician involvement in efforts to improve the outcome of patient care is vital and, as previously noted, we have addressed this issue by proposing the physician involvement requirement at proposed §484.60, "Care planning, coordination of services, and quality of care." We have also addressed this issue by requiring all HHA skilled professionals, which would include physicians employed by or under contract with the HHA, to participate in the HHA's QAPI program (see proposed §484.75). Likewise, we encourage each HHA to consider the voluntary input of physicians who are not employed by or under contract with the HHA in designing, implementing, and evaluating its QAPI program. Physicians not employed by or under contract with the HHA may be in a unique position to provide a HHA's management and care delivery team with structured feedback and insight on ways that performance could be improved. We believe it would be

overly burdensome and beyond the scope of these regulations to require non-employee and non-contract physicians to participate in specific QAPI activities. However, in developing an effective QAPI program, HHAs have found that including a physician in the planning and organization phase has helped to focus and refine the QAPI program.

7. Infection prevention and control (Proposed §484.70)

In the current HHA CoPs, there is no requirement for an HHA-wide infection control program; however the current regulation at §484.12(c) states that the HHA and its staff must comply with accepted professional standards and principles that apply to professionals furnishing services in an HHA. Infection control practices are part of accepted professional standards and principles, and thus should not be new to HHAs. We are proposing to establish a new CoP at §484.70, "Infection prevention and control," because we believe that it is appropriate to address this important issue as a distinct part of the regulatory process. We would organize this new condition under the following three standards: (1) prevention, (2) control, and (3) education.

The effects of infectious and communicable diseases on patient health are significant. In response to this issue, the health care industry developed guidelines and recommendations for managing infection control programs that include health care settings. ("Requirements for infrastructure and essential activities of infection control and epidemiology in out-of-hospital settings: A Consensus Panel report" Association of Professionals in Infection Control (APIC) and the Society for Healthcare Epidemiology of America (SHEA), American Journal of Infection Control 27 (1999)) Additionally, accreditation organizations such as the Joint Commission responded to the issue of

infection control by designing new infection control standards for, among others, home care providers. Other accrediting bodies have also chosen to include infection control requirements in their home care standards as well. Because of the negative impact on patient health and safety posed by infectious and communicable diseases, and the significant amount of attention generated by this issue, we believe that HHAs need to address infection prevention and control in a more comprehensive manner.

We recognize that a HHA cannot be entirely responsible for the maintenance of a completely infection-free environment in an individual's home (where there are variables beyond the control of the HHA). However, by following "current best practices" (for example, following the standard precaution of wearing gloves when handling blood or blood products) in implementing the plan of care, the potential risks of infectious and communicable diseases can be greatly reduced for patients, families, and staff. We propose in §484.70(a) that HHAs follow infection prevention and control best practices, which include the use of standard precautions, to curb the spread of disease.

Under proposed standard §484.70(b), "Control," we would expect the HHA to maintain a coordinated agency-wide program for the surveillance, identification, prevention, control, and investigation of infectious and communicable diseases. (Also see "Definitions for Surveillance of Infections in Home Health Care", February 2008, http://www.apic.org/AM/Template.cfm?Section=Search&section=Surveillance_Definitions &template=/CM/ContentDisplay.cfm&ContentFileID=9898.) Many states have rules requiring reporting of certain communicable diseases to the department of health. In turn, the department of health typically conducts investigations. We would expect HHAs to

work in conjunction with their respective health departments, who work in conjunction with the CDC, when developing and implementing their programs.

Additionally, under this proposal, the program would be expected to be an integral part of the agency's QAPI program. As part of the QAPI program, the infection prevention and control program would identify infectious and communicable disease problems that affect the provision of home health services, track patterns and trends, establish a corrective plan, and monitor for improvement and effectiveness of corresponding interventions.

Because infection prevention and control education is crucial to preventing the spread of communicable diseases, we are proposing an education standard within this CoP at §484.70(c). HHAs would be expected to provide education on "current best practices" to staff, patients, and caregivers. This could be accomplished through in-service training for staff, and through the use of printed material, instructional videos, and in-home demonstration for patients and their families/caregivers. The training provided to patients and caregivers should be specific to their individual needs, such as safe practices for performing assisted monitoring of blood glucose as part of typical diabetes management. (See Infection Prevention during Blood Glucose Monitoring and Insulin Administration at http://www.cdc.gov/injectionsafety/blood-glucose-monitoring.html). The exact content and frequency of staff, patient, and caregiver education would be left to the discretion of individual HHAs, as established in their policies and procedures.

The proposed condition would allow the HHA flexibility in meeting its prevention, control, and education standards. For example, the amount of staff education time needed for infection control would depend on both staff experience and the patient population.

While we would expect "current best practices" to be followed, we are not proposing any specific approaches to meeting this requirement; readers should visit the CDC website at http://www.cdc.gov/HAI/settings/outpatient-care-guidelines.html for more information about core infection control practices that apply to all outpatient health care settings.

We believe that this proposed infection control CoP follows, and is consistent with, the functions of infection control as defined in the APIC/SHEA Consensus Panel report. The report recommended that health care providers intervene directly to prevent infections; obtain and manage critical data and information, including surveillance for infections; develop and recommend policies and procedures; and educate and train health care workers, patients, and nonmedical caregivers. Further, we believe that the three-pronged approach of prevention, control, and education, as outlined in the proposed standards under this CoP, would accomplish the three principal goals of infection control as presented in the Consensus Panel report. These three goals are: (1) protect the patient; (2) protect the health care worker (and others in the health care environment); and (3) accomplish the previous two goals in a manner that is timely, efficient, and cost-effective whenever possible. By maintaining an effective infection prevention and control program that is also an integral part of a QAPI program, a HHA would provide clear evidence of its efforts to minimize the spread of infectious and communicable diseases.

8. Skilled professional services (Proposed §484.75)

This proposed new condition would consolidate and revise current conditions at §484.30, "Skilled nursing services"; §484.32, "Therapy services"; and §484.34, "Medical social services"; and set forth the requirements for skilled professional services. Instead of

specifically identifying tasks, we would broadly describe the expectations of the skilled professionals who participate in the interdisciplinary team approach to home health care delivery. Specifically, we would reduce the regulation's focus on administrative agency process requirements and shift the focus to outcomes of care. Skilled professionals, within this context, would provide services to HHA patients directly as employees of the HHA or under a contractual agreement. We propose that skilled professionals actively participate in the coordination of all aspects of care where appropriate. By doing so, they would become more aware of the need to function as part of an interdisciplinary team.

We have organized this proposed condition into three areas: (1) provision of services by skilled professionals; (2) responsibilities of skilled professionals; and (3) supervision of skilled professional assistants. Skilled professional services, as proposed in §484.75(a), include physician services, skilled nursing services, physical therapy, speech-language pathology services, occupational therapy, and medical social work services. This is consistent with the description of the home health services under the hospital insurance benefits at part 409, subpart E. Provision of services by skilled professionals, as proposed in §484.75(b), would specify that skilled professional services may only be provided by health care professionals who meet the appropriate criteria spelled out in proposed §484.115, "Personnel qualifications," and who practice according to the HHA's policies and procedures.

We propose in §484.75(b), "Responsibilities of skilled professionals," that skilled professionals who provide services to HHA patients directly, or under arrangement, participate in coordinating all aspects of care, including:

- Assuming responsibility for the ongoing interdisciplinary assessment and development of the individualized plan of care in partnership with the patient, representative (if any), and caregiver(s);
- Providing services that are ordered by the physician as indicated in the plan of care;
- Providing patient, caregiver, and family counseling;
- Providing patient and caregiver education;
- Preparing clinical notes;
- Communicating with the physician who is responsible for the home health plan of care and other health care practitioners (as appropriate) related to the current home health plan of care; and
- Participating in the HHA's quality assessment and performance improvement program and HHA-sponsored in-service training.

We believe that an interdisciplinary approach is crucial for meeting the needs of home health patients.

In addition to the requirements for licensed professional services described above, we propose to include a requirement governing the supervision of skilled professional assistants at §484.75(c). This would require a RN identified by the HHA to supervise the care provided by nurses such as licensed vocational nurses and licensed practical nurses. We also propose that all rehabilitative therapy assistant services would be provided under the supervision of a physical therapist (PT) or occupational therapist (OT) who meets the appropriate requirements of §484.115. Furthermore, we believe that it is essential for all

medical social services to be provided under the overall supervision of a MSW-prepared social worker who meets the requirements of §484.115.

9. Home health aide services (Proposed §484.80)

Section 1891(a)(3)(D) of the Act requires the Secretary to establish minimum standards for home health aide training and competency evaluation programs. Section 1861(m)(4) of the Act requires Medicare-covered home health aide services to be furnished only by individuals who have successfully completed a training program approved by the Secretary. Currently, the CoP concerning home health aide services is set forth at §484.36. In this rule, we propose to retain the current requirements while making clarifying and organizational changes to §484.36. As part of our reorganization, this revised condition would be re-located at proposed §484.80.

We also propose to incorporate into this new CoP the provisions concerning the qualification requirements for becoming a home health aide, currently located at §484.4. In this proposed rule, these requirements would now be organized as nine standards under proposed §484.80: (1) home health aide qualifications; (2) content and duration of home health aide classroom and supervised practical training; (3) competency evaluation; (4) in-service training; (5) qualifications for instructors conducting classroom and supervised practical training; (6) eligible training and competency evaluation organizations; (7) home health aide assignments and duties; (8) supervision of home health aides; and (9) individuals furnishing Medicaid personal care aide-only services under a Medicaid personal care benefit.

As noted above, provisions concerning the qualifications for home health aides are

set forth at current §484.4, Personnel qualifications. We believe these specific qualifications would be more appropriately located in the section covering home health aide services. At proposed §484.80(a)(1), we would specify the necessary requirements for an individual to be considered a qualified home health aide. A qualified home health aide would be an individual who has successfully completed one of the following: (1) a training and competency evaluation program that meets the requirements described in §484.80(b) and §484.80(c); or (2) a competency evaluation program that meets the requirements described in §484.80(c); or (3) a nurse aide training and competency evaluation program that is approved by the state as meeting the requirements of §483.151 through §483.154 (State review and approval of nurse aide training and competency evaluation programs) and is currently listed in good standing on the state nurse aide registry; or (4) a state licensure program that meets the requirements described in §484.80(b) and §484.80(c).

In light of the high turnover rate within the home health aide work force, we believe that flexibility in qualification requirements would enable HHAs to recruit qualified aides from a wider pool of employee prospects. While the duties of nurse aides and home health aides are quite similar, the main difference is the environment in which the aides perform the services. An agency's internal policies and procedures would govern the home health aide orientation training to reflect the differences in duties, and the environments in which the duties are performed. HHAs would be free to add additional aide training requirements as desired in order to address any specialized needs within the HHA's patient population (for example, additional skills related to dealing with pediatric patients for HHAs that have pediatric programs).

Under proposed §484.80(a)(2), we would retain the intent of the current requirement at §484.4, and specify when a home health aide is deemed to have completed a program (as specified in proposed §484.80(a)(1) above). This determination would be based on whether, since the most recent completion of a program, there was a period of 24 months or greater since completion of the last home health aide training during which none of the services furnished by the aide were for compensation. We would also stipulate that, if there had been a 24-month or greater lapse in furnishing services, the aide would need to complete another program before the home health aide can provide services, as specified in §484.80(a)(1).

In this rule, we propose to retain the requirements for content and duration of training from current §484.36(a). However, we have clarified this section. We propose, at §484.80(b), to set forth the requirements for training content and its duration, training methods (classroom and practical), and training documentation. Proposed §484.80(b)(1) and (2) regarding home health aide classroom and practical training instructor and duration requirements would be the same as in the current rule. The current regulation at §484.36(a) contains provisions regarding qualifications for instructors of home health aide training and specifies which organizations are eligible to provide training. We would retain and reorganize these two provisions into two separate standards at §484.80(e) and §484.80(f), respectively. In addition, we would remove the definition for "supervised practical training" which appears in the current standard, and move it to a more appropriate place under §484.2, Definitions.

The current requirement at §484.36(a)(1)(i) requires that "communication skills" be

part of the content of training for home health aides. Since home health aides are members of the interdisciplinary team and often visit a patient multiple times each week, they are in a position to observe changes in a patient's status and note the needs that are crucial and relevant to future treatment decisions for that patient. As such, home health aides should be able to report and document these changes in an appropriate manner to ensure that observations of a patient's status are described accurately to ensure optimal care. Therefore, in this proposed rule, we would require at §484.80(b)(3)(i) that communication skills include the aide's ability to read, write, and verbally report clinical information to patients, representatives, and caregivers, as well as to other HHA staff. The intent of this proposed change is to ensure that home health aides would be able to communicate effectively with patients, caregivers, and HHA staff. We would not specify the primary language for employees of HHAs because we recognize that many languages may exist within a community. However, we believe that it is important that the HHA attempt to match patients with staff relative to their abilities to communicate with one another.

We propose to add a new skill requirement related to recognizing and reporting changes in skin condition, including pressure ulcers. Home health aides are often the staff members who have the most frequent in-person contact with patients, and are therefore more likely to be in a position to notice changes in skin condition and early stage pressure ulcers. Early identification and reporting by home health aides would enable early intervention by the HHA to treat and reverse such changes. We believe that this early intervention would be beneficial to patients.

At §484.80(b)(4), we propose to retain the current provision at §484.36(a)(3) with

minor revisions. This provision would require the HHA to maintain documentation that the requirements for content and duration of home health aide classroom and supervised practical training have been met. Similarly, we propose to retain the HHA documentation requirement currently set out at §484.36(b)(5), which requires the HHA to document that the requirements for both the competency evaluation and in-service training have been met. However, as noted above, we are now proposing to reorganize the current standard at §484.36(b) into two separate standards, §484.80(c) Competency evaluation, and §484.80(d) In-service training. Therefore, we propose to incorporate a documentation provision, which would require the HHA to document that the requirements of the standard have been met.

We propose to address various requirements for the competency evaluation of home health aides in §484.80(c). We propose to retain the requirement currently found at §484.36(b)(1), which states that an individual may furnish home health aide services on behalf of an HHA only after the successful completion of a competency evaluation program as described in that section.

As noted in the previous section, we propose to better define the term "communication skills," and would now require communication training as part of the home health aide training program (§484.80(b)(3)(i)). We also propose to include this skill among the subject areas which would be evaluated by observation of the home health aide performing the tasks.

An effective way to assess aide competency is by observing the performance of the aide with a patient. Direct observation of the aide providing services to a patient would

provide assurance that the aide has knowledge and understanding of the task at hand. We believe it would be acceptable to conduct aide training on a mannequin, and to conduct a competency evaluation on a "pseudo-patient." However, the pseudo-patient for the competency evaluation would have to be an individual, such as another aide or volunteer, whose age is representative of the primary population served by the HHA. The following skills would be evaluated: communication skills, reading and recording vital signs, personal hygiene techniques, safe transfer techniques, and normal range of motion and positioning criteria (specified under paragraphs (b)(3)(i), (b)(3)(iii), (b)(3)(ix), (b)(3)(x), and (b)(3)(xi)). The skills would be evaluated by observing the aide's performance carrying out the task with a patient or volunteer. The task would be required to be carried out to completion to assure that the aide was capable of performing tasks thoroughly, correctly, and independently. In accordance with proposed §484.80(c)(2), the competency evaluation described in this paragraph may be offered by any organization, except an HHA that has been subject to certain corrective actions as described in proposed paragraph (f) of this section.

Section 484.80(c)(3) would maintain the current requirement that a RN must perform the competency evaluation. In addition to the RN, we are now proposing that the competency evaluation be done in consultation with other skilled professionals, as appropriate, since we believe it is essential that a home health aide's competency be demonstrated in each specific task performed. However, we continue to believe that it is necessary that a RN actually perform the competency evaluation. Since we depend upon a

RN to provide the foundation of home health aide training, it is necessary to use a RN to evaluate the skills learned in that training.

This rationale for the use of a RN in performing the competency evaluation is also the basis for the proposed change to the current regulation at §484.36(b)(4)(i), which requires that if a home health aide is going to perform a task for which he or she was rated "unsatisfactory," it must be performed under the supervision of a licensed nurse (either a licensed practical nurse or a RN) until he or she achieves an evaluation of "satisfactory." We would modify this requirement at §484.80(c)(4) by requiring that the task be performed under the supervision of a RN, not a licensed practical nurse.

In the current rule, at §484.36(b), the provisions regarding in-service training and competency evaluations of home health aides are combined. We believe that these requirements should be separated into two standards: competency evaluation, as discussed above, at proposed §484.80(c), and in-service training at proposed §484.80(d). Creating two standards would emphasize the importance of each of these areas. We would retain 12 as the minimum number of hours of in-service training required for a 12-month period. The training could occur while an aide was furnishing care to a patient. We continue to believe that requiring 12 hours of training in a 12-month period would not place an unreasonable burden on the resources of the organization furnishing the training. Using the 12-month period would allow HHAs considerable flexibility in scheduling and in providing training. We would expect that the start dates for the 12-month in-service training period would be the aides' dates of hire or calendar year, as defined by the HHA.

The proposed requirements for the home health aide competency evaluation

discussed above, when coupled with this proposed requirement for in-service training, as well as ongoing aide supervision (as proposed in §484.80(h)), would provide an environment conducive to safe and appropriate patient care. Further, by continuing to emphasize ongoing in-service training, HHAs would have the opportunity to develop programs that would promote aide understanding of selective aspects of care and advance aide competency in general. Proposed §484.80(b) would set forth the elements that must comprise home health aide classroom and supervised practical training, thus suggesting that those elements of training should form a basis for ongoing in-service training. Because each HHA is unique and serves various populations, the proposed standard would allow a HHA to tailor its in-service training to the unique needs of the population it serves.

We would retain the requirements in this proposed rule that aide in-service training could be offered by any organization, and that the training would be required to be supervised by a RN. We propose to relocate the requirement that the RN possess a minimum of 2 years of nursing experience, of which at least 1 year is in home health care, to standard (e), Qualifications for instructors conducting classroom and supervised practical training. We continue to believe that RNs with nursing experience in the home health field should be the principal instructors in the basic training of home health aides, since this is the foundation of an aide's education in patient care. Supplemental education, such as in-service training, could be adequately handled by qualified RNs who may not possess as much experience. For some basic aide training, however, individuals other than a RN may be able to provide instruction. When other individuals provide instruction to home health aides, classroom and practical training would be required to be under the general

supervision of a RN who possessed a minimum of 2 years nursing experience, at least 1 year of which would have to be in home health care.

We propose to retain the current requirements at §484.36(a)(2)(i) regarding organizations that offer aide training (generally, HHAs), with some revision and reorganization under a new standard at §484.80(f), "Eligible training and competency evaluation organizations." We propose to retain the current requirement that home health aide training may be provided by any organization, except an organization that falls under one of the exceptions specified in the regulation. These exceptions include, but are not limited to, agencies that have been found out of compliance with the home health aide requirements any time in the last 2 years, agencies that permitted an unqualified individual to function as a home health aide, and agencies that have been found to have compliance deficiencies that endangered patient health and safety. When selecting an outside organization to provide aide training, we encourage HHAs to select organizations with demonstrated knowledge and experience related to the subject matter(s) being taught.

We propose, at §484.80(g), Home health aide assignments and duties, to set forth aide responsibilities and duties, and are retaining most of current §484.36(c), Assignment and duties of the home health aide. However, we would make revisions to further support an interdisciplinary approach to care (as typified here and in §484.60, Care planning, coordination of services, and quality of care).

Proposed §484.80(g)(1) would provide that the home health aide would be assigned to a specific patient by the RN or other appropriate skilled professional (that is, physical therapist, speech-language pathologist, or occupational therapist). This proposed revision

reflects an interdisciplinary team approach by adding the opportunity for additional skilled professionals to designate home health aide assignments. To the extent possible, we believe that there should be consistent assignment of aides to patients in order to facilitate continuity of care and communication. Currently, under §484.36(c)(1), an appropriate skilled professional responsible for the supervision of the home health aide may provide only written patient care instructions for the home health aide. A RN is solely responsible for the assignments of home health aides to specific patients. However, we believe, for example, that if a patient is receiving physical therapy services, then the appropriate skilled professional (for example, a physical therapist) should be allowed to assign an aide to this patient. This is consistent with the current requirement at §484.36(c) which require that the written patient care instructions for the home health aide be prepared by the appropriate professional responsible for the supervision of that home health aide. The ability to assess patients and take into account the many aspects of the patient's functioning would allow the RN or other skilled professional to identify patient needs, and match the skills of a particular home health aide to those needs.

Proposed §484.80(g)(2) would require that the home health aide provide services that are ordered by the physician in the plan of care, that the home health aide is permitted to perform under state law, and that are consistent with the home health aide training. Home health aides could not furnish services outside of their scope of practice as defined by local and state laws, and the HHA's internal policies. In §484.80(g)(3), we propose to retain the inclusive listing of duties for home health aides currently under §484.36(c)(2).

At §484.80(g)(4), we propose a requirement that home health aides be members of

the interdisciplinary team, must report changes in the patient's condition to a RN or other appropriate skilled professional, and must complete appropriate records in compliance with the HHA's policies and procedures. As part of the interdisciplinary team, home health aides would be required to communicate to a RN or qualified therapist observations and experiences when caring for patients. Home health aides may observe changes in patient needs that are crucial to future treatment decisions, and these changes should be reported to the appropriate HHA professional in order to implement effective and appropriate changes in care. Under proposed §484.80(g)(4), our intention is to reflect an interdisciplinary approach to care. In this case, the provision would emphasize the home health aide's role as a member of the interdisciplinary team. Because an aide may be the member of the home health team who is most often in the home with the patient, the aide may be the one most likely to note changes in a patient's condition. As observation skills are a required content area in aide training (see §484.80(b)(3)(ii)), we would expect that aides be taught to identify any changes that may need to be reported to the RN or other skilled professional.

On-going home health aide supervision, as described in proposed §484.80(h), "Supervision of home health aides," is a necessary component of quality care for HHAs, and ensures that services provided by home health aides are in accordance with the agency's policies and procedures and in accordance with state and federal law. In this proposed standard, we would differentiate the aide supervision requirements based on the skill level of the care required by the patient. In proposed §484.80(h)(1), we propose that if a patient is receiving skilled care, the home health aide supervisor (RN or therapist) must make an onsite visit to the patient's home no less frequently than every 14 days. The home

health aide would not have to be present during this visit. If a potential deficiency in home health aide service was noted by the home health aide supervisor, then the supervisor would have to make an on-site visit to the location where the patient was receiving care in order to observe and assess the home health aide while he or she is performing care. In addition to the regularly scheduled 14-day supervision visits and the as-needed observation visits, HHAs would be required to make an annual on-site visit to a patient's home to observe and assess each home health aide while he or she is performing patient care activities. The HHA would be required to observe each home health aide with at least one patient, and would be allowed to increase the number of home health aide-patient interaction observations as necessary to assure a full assessment of the aide's patient care knowledge and skills.

In proposed §484.80(h)(2), we would require that if home health aide services are provided to a patient who is not receiving skilled care, the RN must make an on-site visit to the location where the patient is receiving care no less frequently than every 60 days in order to observe and assess each home health aide while he or she is performing care.

Irrespective of the 14-day and 60-day requirements, the agency would be responsible for maintaining appropriate supervision of a home health aide, and could utilize more frequent supervision at its discretion (for example, when a home health aide learns new skills). The HHA would also be expected to increase supervisory oversight for those home health aides for whom a request for supervision had been made either by the patient, representative, caregiver, or a family member.

At proposed §484.80(h)(3), we would require that if a deficiency in home health

aide services was verified by the home health aide supervisor during an on-site visit, then the agency would have to conduct, and the home health aide would have to complete, a competency evaluation in accordance with paragraph (c) of this section. This proposed requirement would allow agencies to re-teach and reassess important home health aide skills to ensure that the home health aide provided safe and effective care to all patients at all times.

We also propose to add a new paragraph at §484.80(h)(4) to ensure that home health aide supervision visits focus on the aide's ability to demonstrate initial and continued satisfactory performance in meeting essential criteria. Supervision visits would be required to assess the home health aide's success in following the patient's plan of care; completing tasks assigned to the home health aide; communicating with the patient, representative (if any), caregivers, and family; demonstrating competency with assigned tasks; complying with infection prevention and control policies and procedures; reporting changes in the patient's condition; and honoring patient rights.

We would not set forth a specific requirement relative to the method of documenting the supervisory visit, but we expect that the HHA would develop a method of documentation that best fit its needs. Proposed §484.80(h)(5) would retain, with minor revisions, the current requirements found under §484.36(d)(4) as they relate to the HHA's responsibilities for home health aides who are furnishing services under arrangement (that is, the aides are not employees of the HHA). The HHA would be required to ensure the quality of home health aide services, supervise aides as proposed in this section, and ensure that aides have met the training and competency evaluation requirements of this proposed

part.

At proposed §484.80(i), Individuals furnishing Medicaid personal care aide-only services under a Medicaid personal care benefit, we propose to retain the requirements at current §484.36(e), with some minor clarifying revisions. Under this provision, a Medicare-certified HHA that provides personal care aide services to Medicaid patients under a State Medicaid personal care benefit would be required to determine and ensure the competency of individuals for those Medicaid-approved services performed. Placing this requirement within the HHA CoPs would afford protections to all individuals served in that setting, regardless of payer source. The requirements are designed to protect the patient, and are consistent with §440.167(a), which states that patients receiving personal care services in their home are required to have a physician's authorization in accordance with a plan of treatment or a service plan approved by the state. Changes in the overall language of this provision would be made for the sake of clarity. In addition, the reference to §440.170 in the current regulation at §484.36(e)(2) is incorrect; it should read §440.167. Therefore, we propose to make the necessary correction.

D. Proposed Subpart C, Organizational Environment

1. Compliance with Federal, State, and local laws and regulations related to health and safety of patients (Proposed §484.100)

Provisions concerning compliance with federal, state, and local laws are presently located at current §484.12, "Condition of Participation: Compliance with Federal, State and local laws, disclosure and ownership information, and accepted professional standards and principles." We propose to retain most of the provisions contained in this condition

with minor changes, which are discussed below. This proposed condition would now be set forth at §484.100.

We propose to incorporate the standard at current §484.12(a) into the general opening statement of the condition at §484.100. At proposed §484.100(a), we would continue to require HHAs to comply with the requirements of part 420, subpart C by disclosing the names and addresses of all persons with an ownership or controlling interest, the name and address of each officer, director, agent, or managing employee, and the name and address of the entity responsible for the management of the HHA along with the names and addresses of the CEO and chairperson of the board of that entity. Section 1126(b) of the Act, codified in regulations at §420.201 of our rules, specifies that the term "managing employee" means an individual, including a general manager, business manager, administrator, or director, who exercises operational or managerial control over the entity, or who directly or indirectly conducts the day-to-day operations of the entity. Accordingly, for purposes of this rule, "director" would refer to a corporate director and not a medical director or nursing director. Section 420.201 defines an "agent" as any person who has been delegated the authority to obligate or act on behalf of a provider. In this rule, we would intend an "officer" to be any person who is responsible for the overall management of the operation of the HHA; we also would require that the HHA provide information on all individuals who are officers of the HHA under the law of the state in which the HHA is incorporated. Because the business address of an agency is self-explanatory, the additional address we would request in the standard would refer to a residential address for all individuals to whom the rule applies. A Post Office Box address

would not be considered a business or residential address and would not be satisfactory for purposes of compliance with this proposed requirement.

We propose to remove the provisions regarding state licensure from current paragraph §484.12(a) and incorporate them into the proposed state licensure standard at §484.100(b). Under the provisions of proposed §484.100(b), a HHA, its branches, and its staff would be licensed, certified, or registered, as applicable, by the state licensing authority if the state had established licensure requirements. In addition, the Act at §1861(o)(4) requires that a HHA, which would include a branch, must be licensed, or approved as meeting the standards established for licensing, in any state in which state or local law provides for the licensing or other approval of HHAs and their subsidiaries. If a state requires a HHA to have a license, then we would require that the provider be in compliance with that state's law or regulation. In addition, state licensure requirements are enforced at the state level and would be subject to state jurisdiction. Therefore, the provisions of this proposed rule would not affect providers that have been granted waivers of state requirements.

State surveyors are not, and have never been, responsible for citing HHAs for violating the rules of regulatory bodies other than the State or CMS. When a HHA is found to be out of compliance with a federal, state, or local law by another regulatory agency with jurisdiction and authority to cite noncompliance (for example, OSHA or the Department of Justice), CMS decides whether that violation should also constitute a violation of the HHA CoPs. Both the title of this proposed CoP and its introductory paragraph would refer to only those federal, state, and local laws and regulations which were "related to the health

and safety of patients." We would cite agencies when the violation of federal, state, or local laws or regulations could potentially affect the health and safety of the HHA's patients, and the rights and well-being of patients.

Finally, we propose to move the current requirements at §484.14(j), Laboratory services, to §484.100(c). Because this standard covers compliance with a federal regulation, we believe that it would be better suited under this proposed CoP governing compliance with federal, state, and local laws rather than under its current location at the end of the CoP covering organization, services, and administration of an HHA. Section 484.100(c) would require that HHAs engaged in certain types of lab testing, with an appliance that has been approved for that purpose by the Food and Drug Administration, conduct testing in compliance with the requirements of 42 CFR part 493 (Laboratory Requirements).

This section would also prohibit HHAs from substituting their own self-administered testing equipment, such as glucometers, in lieu of a patient's self-administered testing equipment when assisting a patient in administering the test. We propose this requirement to ensure that patients have access to their test results on their own equipment that is maintained in their home. This would allow patients to track their results over time and better understand the impact of their behaviors and choices upon their test results. Such understanding is an important step in fostering patient independence and positive patient outcomes. Agencies may use their own self-administered testing equipment as a complement to a patient's self-administered testing equipment when assisting a patient in administering the test when there is reason to believe that the patient's

self-administered testing equipment is inaccurate. In this situation, we would expect the HHA to assist the patient in obtaining accurate testing equipment for future use. Agencies may also use their own self-administered testing equipment for a short, defined period of time when the patient has not yet obtained his or her own testing equipment, such as in the days immediately following physician orders to obtain the testing equipment when a patient may not have the time and resources immediately available to complete the process. We would expect the HHA to use available resources to assist the patient in obtaining his or her own testing equipment as quickly as possible.

In addition, this section would provide that if the HHA chose to refer specimens for laboratory testing, the referral laboratory would have to be certified in accordance with the applicable requirements of part 493. The laboratory services standard is a federal requirement in accordance with the Clinical Laboratory Improvement Amendments of 1988 (CLIA). We are not proposing to alter the intent or meaning of this provision.

2. Organization and administration of services (Proposed §484.105)

This proposed CoP on organization and administration of services would revise current regulations at §484.14, "Organization, services, and administration." As previously discussed, the current regulation at §484.14(g), "Coordination of patient services," would be relocated and revised under proposed §484.60. In addition, the current regulations found at §484.38, "Qualifying to furnish outpatient physical therapy or speech pathology services," would be relocated to §484.105. The proposed new condition would simplify the structure of the current requirements, and focus on both essential organizational structures and performance expectations for the administration of HHA operations. With

the diffusion of home health organization and management structures (currently, there are 2,660 branches distributed among 1,301 parent HHAs nationwide), this proposed rule would help to ensure accountability by assisting agencies in setting performance expectations that we believe would lead to a higher level of quality for patients. The overall goal of the proposed condition is to produce a clear, accountable organization, management, and administration of a HHA's resources to attain and maintain the highest practicable functional capacity for each patient's medical, nursing, and rehabilitative needs, as indicated in the plan of care. Attaining and maintaining the highest practicable functional capacity for each patient is the primary goal of HHA services based on the premise that the role of the HHA is to assist each patient in overcoming any deficits that lead to his or her need for home health services. HHAs provide services, supplies, and education to patients, making every effort to encourage and support patient autonomy, self-care, self-management, and ultimately discharge from the HHA.

Under the current requirements found at §484.14(b), we would expect the governing body to be able to assess the HHA's financial needs and to assume responsibility for effectively managing its financial resources. We would maintain the intent of this requirement, at proposed §484.105(a), "Governing body," and would expand the responsibilities of the governing body to assume full legal authority and responsibility for the agency's overall management and operation, the provision of all home health services, the review of the budget and operational plans, and the agency's quality assessment and performance improvement program, in addition to responsibility for the agency's fiscal operations, as retained from the current regulations.

Proposed §484.105(b), "Administrator," would describe the role of the administrator and provisions for when the administrator is not available. We propose that the administrator be appointed by the governing body, be responsible for all day to day operations of the HHA, and be responsible for ensuring that a skilled professional as described in §484.75 is available during all operating hours. The current State Operations Manual (Pub 100-7, Appendix B, http://cms.hhs.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/som107ap_b_hha.pdf) describes the concept of being available during operating hours as being on the premises of the HHA or by reachable via telecommunications. HHA management would have discretion to structure the implementation of this concept to suit the organization's needs. In addition, the current State Operations Manual also describes the concept of "operating hours" as all hours that staff from the agency is providing services to patients. Because HHAs are already familiar with these concepts, we are not proposing to change our interpretations.

While we would expect the administrator to be available during all operating hours to take an active role in the daily operations of the HHA, we recognize that there are times when the administrator cannot be available. We propose that, any time when the administrator is not available, a pre-designated person, who is authorized in writing by the administrator and governing body, would assume the same responsibilities and obligations as the administrator, including the responsibility to be available during all operating hours. The pre-designated person may be the same skilled professional described above. We note that, in addition to this requirement, we also propose personnel requirements for the administrator at §484.115(a). The administrator, and the pre-designated person, would be

required to meet these personnel requirements.

In addition to the overall management of the HHA by the governing body and the administrator, we propose a new clinical manager role at §484.105(c). The clinical manager would be a qualified licensed physician or registered nurse, identified by the HHA, who is responsible for the oversight of all personnel and all patient care services provided by the HHA, whether directly or under arrangement, to meet patient care needs. The supervision of HHA personnel would include assigning personnel, developing personnel qualifications, and developing personnel policies. Oversight of the services provided to patients would include, but would not be limited to, assigning clinicians to patients; coordinating care provided to patients by the various patient care disciplines; coordinating referrals within the HHA; assuring that patient needs are continually assessed; and assuring that patient plans of care are developed, implemented, and updated. We believe that the clinical manager role is essential for managing the complex, interdisciplinary care of home health patients, and that the responsibilities included in this new standard are not currently fulfilled. Six of the 20 most frequently cited survey deficiencies center on the need for patient care coordination and implementation, including the most frequently cited deficiency related to ensuring that each patient has a written and updated plan of care. These frequent deficiency citations indicate that patient care is not being sufficiently planned, coordinated, and implemented to ensure the highest quality care for all HHA patients at all times. We believe that having a designated clinical manager will address this need while assuring that agency personnel standards are upheld.

In §484.105(d), we propose a new standard, Parent-branch relationship. As discussed previously in the "Definitions" section of this preamble, we would change the definition of "branch" in §484.2 to define a branch office as a location or site from which a HHA provides services within a portion of the total geographic area served by the parent agency. We would delete the portion of the definition referring to a branch location that is "sufficiently close" to the parent agency, because section 506(a)(1) of the Medicare, Medicaid and State Children's Health Insurance Program Benefits Improvement and Protection Act of 2000 (Pub. L. 106-554) (BIPA) mandated that neither time nor distance between a parent office of the HHA and a branch office shall be the sole determinant of a HHA's branch office status. However, both time and distance can still be considered as factors in conjunction with other considerations.

We believe that the focus should be on the ability of the parent HHA to demonstrate that it can monitor all services provided in its entire service area, furnished by any branch offices, to ensure compliance with the CoPs. The decision to approve a branch is based on the HHA's ability to assure that the quality and scope of items and services provided to all patients from the branch meets each patient's medical, nursing, and rehabilitative needs. Thus, we would expect that the lines of authority and professional and administrative control be clearly delineated in the HHA's organizational structure and in practice. The HHA parent should be aware of the staffing, patient census and any issues/matters affecting the operation of the branch. Furthermore, the administrator of the HHA must be able to maintain an ongoing liaison with the branch to ensure that staff is competent and able to provide appropriate, adequate, effective and efficient patient care so as to ensure that any

clinical and/or other emergencies are immediately addressed and resolved. The HHA parent must be able to monitor branch activities (clinical and administrative) and the management of services, as well as personnel and administrative issues, including providing ongoing in-service training to ensure that all staff is competent to provide care and services. The HHA parent is responsible for any contracted arrangements with other individuals or organizations, even when the contracted services are used exclusively by the branch. We would also expect the HHA to be able to demonstrate its ability to ensure that patients being served by all offices consistently receive all necessary and appropriate care and services described in the plans of care. As part of the decision-making process, we will also consider an HHA's past compliance history and all relevant state issues and recommendations. These and other considerations in governing parent-branch relationships were previously included in a Survey and Certification memorandum (Requests for Home Health Agency Branch Office Approval and the Use of a Reciprocal Agreement, S&C-02-30, issued May 10, 2002), and will inform future CMS subregulatory guidance on this topic.

We provide guidance for approving a branch office in §2182.4B of the State Operations Manual. In addition, we assign identification numbers to every existing branch of a parent HHA and subunit. The identification system is implemented nationally, and uniquely identifies every branch of every HHA certified to participate in the Medicare home health program. It also links the parent to the branch. The branch identification number is also required on the OASIS assessments. This allows a HHA access to outcome reports that help it differentiate and monitor the quality of care delivered down to the

branch level. (We note that although this information is available to HHAs, information is not broken down by branch when generating Home Health Compare results that are available to the general public.) Through this method of monitoring how services are furnished by its branches, the parent HHA can strengthen the parent-branch relationship and further ensure the quality of care delivered to its patients. We would also add to our regulations the requirement that HHAs report their branch locations to the state survey agency at the time of a HHA's initial certification request, at each survey, and at the time any proposed additions or deletions were made. This proposed rule would eliminate the "subunit" designation. An existing subunit currently operates under a distinct Medicare provider number and would be considered to be a distinct HHA upon implementation of this final rule, with its own governing body and administrator that is not shared with another HHA. Depending on state-specific laws and regulations, this regulatory change may allow a subunit to apply to become a branch office of a parent HHA if the parent could provide "…direct support and administrative control of the branch."

In accordance with section 1861(m) of the Act, a HHA may provide its services directly and/or under arrangement with another agency or organization. The agency providing services under arrangement may not have been denied Medicare enrollment; been terminated from Medicare, another Federal health care program, or Medicaid; had its Medicare or Medicaid billing privileges revoked; or been debarred from participating in any government program. Therefore, the current requirement at §484.14(h) governing services under arrangement would be retained with a minor revision in the proposed standard at §484.105(e), Services under arrangement. We propose to require that the

primary HHA have a written agreement with another agency, with an organization, or with an individual, that it has contracted with to provide services to its patients, which stipulates that the primary HHA would maintain overall responsibility for all HHA care provided to a patient in accordance with the patient's plan of care, whether the care is provided directly or under arrangement. If the primary HHA chooses to furnish some services under arrangement, then it retains management, service oversight, and financial responsibility for all services that are provided to the patient by its contracted entities. All services provided by contracted entities would be authorized by the primary HHA, and furnished in a safe and effective manner by qualified personnel. In addition to this revision, we would correct a typographical error in the cross-reference citation for the United States Code.

We propose to move the current standard at §484.14(a), "Services furnished," to §484.105(f)(1). According to section 1861(o) of the Act, for purposes of participation in the Medicare program, a HHA is defined as being "primarily engaged in providing skilled nursing services and other therapeutic services," without reference to the services being provided on a part-time or intermittent basis as provided in the current regulation. Although certain payment-related requirements make reference to the intermittent nature of HHA services, the phrase "part-time or intermittent" is not used in the statutory definition of an HHA. In order to more closely align with the statutory definition, we propose to delete it from this standard. However, the use of the term "part-time or intermittent" would continue to exist under the coverage and eligibility requirements for home health services.

As stated in proposed §484.105(f)(1), skilled nursing and one of the therapeutic services must be made available on a visiting basis in the patient's home. At least one

service would be required to be provided directly by the HHA. This is a current requirement and would be retained. Other services could be offered under arrangement with another agency or organization. It should be noted that while HHAs may provide other services such as continuous nursing care either directly or under arrangement, those additional services might not be eligible for coverage under the Medicare program.

Additionally, we propose to retain the requirements of current §484.12(c), "Compliance with accepted professional standards and principles," at §484.105(f)(2). We would continue to require that HHAs furnish all services in accordance with accepted professional standards of practice. We would also propose to require that all HHA services be provided in accordance with current clinical practice guidelines. We believe that this addition is necessary to ensure that HHA patients receive care that is based on clinical evidence, where available, and up-to-date medical practices.

Within this proposed CoP, we are moving current §484.38, "Qualifying to furnish outpatient physical therapy or speech pathology services," to §484.105(g). We believe that this requirement would be more appropriately codified as a standard (now titled "Outpatient physical therapy or speech-language pathology services") following the "Services furnished" standard under this proposed CoP. We propose to make no other changes to this standard.

Finally, we propose to retain the "Institutional planning" standard currently located at §484.14(i) and as required for HHAs under §1861(z) of the Act. We would retain this standard at §484.105(h) without any revisions.

3. Clinical records (Proposed §484.110)

In this section of the preamble we describe: (A) changes to the conditions of participation related to clinical record requirements; and (B) the HHS policy priority to accelerate interoperable health information exchange including through the use of certified electronic health record technology.

(A) Changes to the conditions of participation related to clinical record requirements.

This proposed section would retain, with some additional clarification, many of the long-standing clinical record requirements currently found at §484.48. In this condition, we propose to retain only those process requirements which provide essential patient health and safety protection.

The primary requirement under the proposed clinical records CoP would be that a clinical record containing pertinent past and current relevant information would be maintained for every patient who was accepted by the HHA to receive home health services. We propose to add the requirement that the information contained in the clinical record would need to be accurate, adhere to current clinical record documentation standards of practice, and be available to the physician who is responsible for the home health plan of care and appropriate HHA staff. The information could be maintained electronically. The clinical record would be required to exhibit consistency between the diagnosed condition, the plan of care, and the actual care furnished to the patient. Consistency would be reflected in the appropriate link between patient assessment information and the services and treatments ordered and furnished in the plan of care. In light of the decentralized nature of HHAs (that is, patient care is not furnished in a single location), we believe that members of the interdisciplinary team must have access to patient information in order to

provide quality services. Many HHAs maintain electronic records, and we recognize that this technological change in home health care industry can provide all members of the interdisciplinary team access to important patient care information on an ongoing basis.

Proposed §484.110(a), "Contents of clinical record," contains several elements that are part of the current clinical record requirement. We propose to retain the requirement that the record include clinical notes, plans of care, physician orders, and a discharge summary. To give HHAs flexibility in maintaining clinical records, we propose to no longer specifically require that the name of physician and drug, dietary, treatment, and activity orders be included in a dedicated part of the clinical record, since these items would already have been made part of the plan of care, and thus would already be included in the clinical record. We also propose to add requirements to this standard that reflect our outcome-oriented approach to patient care. Specifically, at proposed §484.110(a), we would require that the clinical record include: (1) the patient's current comprehensive assessment, including all of the assessments from the most recent home health admission, clinical visit notes, and individualized plans of care; (2) all interventions, including medication administration, treatments, services, and responses to those interventions, which would be dated and timed in accordance with the requirements of proposed §484.110(b); (3) goals in the patient's plan of care and the progress toward achieving the goals; (4) contact information for the patient and representative (if any); (5) contact information for the primary care practitioner or other health care professional who will be responsible for providing care and services to the patient after discharge from the HHA; and (6) a discharge or transfer summary note that would be sent to the patient's primary care

practitioner or other health care professional who will be responsible for providing care and services to the patient after discharge from the HHA within 7 calendar days, or, if the patient is discharged to a facility for further care, to the receiving facility within 2 calendar days of the patient's discharge or transfer. We believe that these timeframes are necessary to assure that providers assuming responsibility for the care of discharged patients have timely information about the patient's recent care, services, and medications. We request public comment regarding these timeframes. Specifically, we would like to know if these timeframes are adequate to assure a smooth transition of care. We would also like to know whether current HHA record systems are capable of producing a discharge summary in a shorter period of time, such as the same day that a patient is discharged.

We believe that these requirements are the minimum necessary for a meaningful clinical record, and that they would still provide the HHA with flexibility in maintaining the clinical record while ensuring that the record contains information necessary for providing high quality patient care. HHAs may choose to maintain additional information in the record which reflects activity pertinent to the patient and his or her care.

We propose to add a new standard at §484.110(b) to require authentication of clinical records. We would require that all entries be legible, clear, complete, and appropriately authenticated, dated, and timed. Appropriate authentication refers to the process of identifying the person who has made an entry into the clinical record and that person's acknowledgement, by a signature and a title, or use of an electronic identifier, that he/she is responsible for the content, accuracy, and completeness of the entry. Authentication for every entry would be required to include a signature and a title, or a

secured computer entry by a unique identifier, of a primary author who had reviewed and approved the entry. This provision would allow HHAs to establish clear policies about clinical record entries and corrections. It is preferred that the original clinician make any necessary corrections to his or her entries to ensure continuity and consistency within the clinical record. In cases where the original clinician is unable to correct his or her entry, we would expect to see documentation of communication with the original clinician regarding modifications to the original entry. We believe it is important to retain flexibility to accommodate the variation in types of documentation and decision making used throughout the industry, and the need to allow HHAs to innovate and improve documentation, including using electronic record formats, without unnecessary restrictions.

Under proposed §484.110(c), we would revise the current requirements under §484.48(a), "Retention of records." With proposed §484.110(c)(1), we would revise the provision regarding the timing of the 5-year clinical record retention period. We do not believe that the current provision, which predicates the beginning of the 5-year retention period on when the cost report is filed with the intermediary, ensures patient safety. Therefore, we have simplified the provision to now require that clinical records be retained for 5 years after the discharge of the patient, unless state law stipulates a longer period of time. In addition to these proposed clinical record retention requirements, HHAs would be expected to continue to comply with other Medicare or Medicaid record requirements for payment purposes.

We would continue to require, in §484.110(c)(2), that HHA policies provide for retention of records even if the HHA discontinues operations. However, we also propose

that the HHA would be required to notify the state agency as to where the agency's clinical records would be maintained. We also propose at §484.110(d) to incorporate into this condition the requirement under current §484.48(b), "Protection of records," relative to the safeguarding of information. At proposed §484.110(d), we would require that clinical records, their contents, and the information contained therein, be safeguarded against loss or unauthorized use. We believe that the requirement under current §484.48(b), concerning the release of clinical record information, is best incorporated into the proposed standard at §484.50(e), Right to confidentiality of clinical records, as noted earlier in this preamble.

Finally, under this clinical records condition, we would add a new standard at §484.110(e), Retrieval of clinical records. We propose that a patient's clinical records (whether hard copy or electronic) be made readily available to a patient or appropriately authorized individuals or entities upon request. The provision of clinical records to those outside of the HHA would be required to be in compliance with the rules regarding personal health information set out at 45 CFR parts 160 and 164.

We note that 45 CFR 164.512 provides for certain "disclosures required by law" without the permission of the patient. We believe that this standard is necessary for two main reasons. First, we believe that the prompt retrieval of patient records is essential to assuring communication, continuity and quality of care within the HHA, as well as between the HHA and other health care entities furnishing care to the patient. Second, in order to enable state surveyors to effectively assess HHA compliance with these regulations, and to enable the quality improvement organizations to fulfill their role in the beneficiary complaint process, timely retrieval of clinical records is essential.

(B) HHS Policy Priority to Accelerate Interoperable Health Information Exchange, including Use of Certified Electronic Health Record Technology.

HHS believes all patients, their families, and their healthcare providers should have consistent and timely access to their health information in a standardized format that can be securely exchanged between the patient, providers, and others involved in the patient's care. (cite: HHS August 2013 Statement, "Principles and Strategies for Accelerating Health Information Exchange.") The Department is committed to accelerating health information exchange (HIE) through the use of electronic health records (EHRs) and other types of health information technology (HIT) across the broader care continuum through a number of initiatives including: (1) alignment of incentives and payment adjustments to encourage provider adoption and optimization of HIT and HIE services through Medicare and Medicaid payment policies, (2) adoption of common standards and certification requirements for interoperable HIT, (3) support for privacy and security of patient information across all HIE-focused initiatives, and (4) governance of health information networks. These initiatives are designed to improve care delivery and coordination across the entire care continuum and encourage HIE among all health care providers, including professionals and hospitals eligible for the Medicare and Medicaid EHR Incentive Programs and those who are not eligible for the EHR Incentive Programs. To increase flexibility in the regulatory certification structure established by the Office of the National Coordinator for Health Information Technology (ONC) and expand HIT certification, ONC has proposed a voluntary 2015 Edition EHR Certification rule (http://www.gpo.gov/fdsys/pkg/FR-2014-02-26/pdf/2014-03959.pdf) to more easily

accommodate HIT certification for technology used by other types of health care settings where individual or institutional health care providers are not typically eligible for incentive payments under the EHR Incentive Programs, such as home health agencies, and other long-term and post-acute care and behavioral health settings.

We believe that HIE and the use of certified EHRs by home health agencies (and other providers ineligible for the Medicare and Medicaid EHR Incentive programs) can effectively and efficiently help providers improve internal care delivery practices, support management of patient care across the continuum, and enable the reporting of electronically specified clinical quality measures (eCQMs). More information on the identification of EHR certification criteria and development of standards applicable to home health agencies can be found at the following locations:

- http://healthit.gov/policy-researchers-implementers/standards-and-certification-regulations
- http://www.healthit.gov/facas/FACAS/health-it-policy-committee/hitpc-workgroups/certificationadoption
- http://wiki.siframework.org/LCC+LTPAC+Care+Transition+SWG
- http://wiki.siframework.org/Longitudinal+Coordination+of+Care

In 2012, ONC sought public comment on whether it should focus any certification efforts towards the health IT used by health care providers that are ineligible to receive incentives under the EHR Incentive Programs. In the regulations establishing the 2014 Edition of health IT standards and EHR certification criteria

(http://www.gpo.gov/fdsys/pkg/FR-2012-09-04/pdf/2012-20982.pdf), ONC concluded, "… that it makes good policy sense to support interoperability and the secure electronic exchange of health information between all health care settings. We believe the adoption of EHR technology certified to a minimal amount of certification criteria adopted by the Secretary can support this goal. To this end, we encourage EHR technology developers to certify EHR Modules to the transitions of care certification criteria (§170.314(b)(1) and §170.314(b)(2)) as well as any other certification criteria that may make it more effective and efficient for EPs, EHs, and CAHs to electronically exchange health information with health care providers in other health care settings. The adoption of EHR technology certified to these certification criteria can facilitate the secure electronic exchange of health information." ONC has also published, "Certification Guidance for EHR Technology Developers Serving Health Care Providers Ineligible for Medicare and Medicaid EHR Incentive Payments" (http://www.healthit.gov/sites/default/files/generalcertexchangeguidance_final_9-9-13.pdf).

In 2013, the Department of HHS requested information on how to accelerate interoperable health information exchange including with long-term and post-acute care providers. The public offered several recommendations for the use of EHR certification and the expansion of the ONC HIT Certification Program (See http://www.healthit.gov/sites/default/files/acceleratinghieprinciples_strategy.pdf. See page 5 for a summary of these recommendations). Among the suggested recommendations from the public was to make certified EHR technology available to long-term and post-acute

providers (and other providers not eligible for the Medicare and Medicaid EHR Incentive Programs).

In the fall of 2013, ONC requested that the HIT Policy Committee (a Federal advisory committee established under the HITECH legislation and responsible for advising the National Coordinator for Health Information Technology on the development, harmonization, and recognition of standards, implementation specifications, and EHR certification criteria) to begin exploring the expansion of certification under the ONC HIT Certification Program, particularly focusing on EHR certification for the long-term and post-acute care and behavioral health care settings. The Certification/Adoption Workgroup of the HIT Policy Committee is expected to present its recommendations to the HIT Policy Committee in the spring of 2014. The full Health IT Policy Committee will make recommendations to the ONC in summer 2014.

As noted, the ONC publishes rules for health IT standards and EHR certification criteria. A key standard adopted in the 2014 Edition Final Rule was the HL7 Consolidated CDA (CCDA) standard. The CCDA is now the single standard permitted for certification and the representation of summary care records. This standard is used for the exchange of Summary Care Records at times of transition in care (for example, discharge) and making available clinical information to patients.

Activities have been undertaken to update the CCDA. The Standards and Interoperability Framework, Longitudinal Coordination of Care (S&I LCC WG) has worked to address gaps in the CCDA to better support the interoperable exchange of documents and content needed at times of transitions in care and referrals in care, and for

the exchange of care plans, including the home health plan of care. The S&I LCC WG is a public/private collaboration. Members of this workgroup included representatives of the National Association of Home Care, Home Care Technology Association of America, the Visiting Nurse Service of New York, and many other clinicians, researchers, vendors, and government representatives. The updates to the CCDA were balloted by HL7 in the fall 2013, and comments have been reconciled. HL7 is expected to publish the CCDAr2 in spring 2014.

On February 26, 2014 ONC published the proposed rule for the 2015 Edition of Health IT standards and EHR certification criteria. The ONC 2015 Edition proposed rule proposes an updated version for the CCDA, the CCDA® Release 2 (CCDAr2). The CCDAr2 includes enhancements to more completely support interoperability for documents needed at times of transitions and referral in care and care plans, including the home health plan of care. The CCDAr2 includes new sections for: Goals; Health Concerns; Health Status Evaluation/Outcomes; Mental Status; Nutrition; Physical Findings of Skin; and many other entries.

We encourage home health providers to use, and their health IT vendors to develop, ONC-certified HIT/EHR technology to support interoperable health information exchange with physicians, hospitals, other LTPAC providers, and with their patients. We anticipate that the use of certified HIT/EHR technology will help improve quality and coordination of care, and reduce costs.

4. Personnel qualifications (Proposed §484.115)

Currently, provisions concerning the qualifications of HHA personnel are located at

§484.4. This section provides very specific credentialing requirements that all staff are required to meet. While we are retaining most of these current personnel qualification requirements, we propose revisions to the organization of the "Personnel qualifications" CoP. Many other provider types cross-reference the HHA personnel requirements, and we are proposing conforming amendments accordingly.

Under our proposed reorganization of part 484, personnel qualifications would be located at §484.115. Personnel qualifications would be set out as general qualification requirements (which would cover all personnel), and personnel qualifications when state licensing laws or state certification or registration requirements exist (which would cover the additional requirements to practice under and in accordance with state laws, and which would cover all personnel where applicable). The proposed personnel qualifications CoP is discussed in detail below.

This proposed standard would consist of all personnel qualifications found under current §484.4, with the exception of those for public health nurses. Except as noted below, we propose to retain the current personnel qualifications for the following professions: administrator, audiologist, home health aide, licensed practical nurse, occupational therapist, occupational therapy assistant, physical therapist, physical therapist assistant, physician, registered nurse, social work assistant, and social worker.

We propose to delete the current qualification category for public health nurses because public health nurses are RNs, and the qualifications for RN are already included in this section. We also propose to replace the term "practical (vocational) nurse," currently found in §484.4, with the more widely used and accepted term, "licensed practical nurse."

The proposed qualifications for a licensed practical nurse would be a person who has completed a practical nursing program, and who furnishes services under the supervision of a qualified registered nurse. Currently, the requirements for the supervision of licensed practical nurses, occupational therapy assistants and physical therapist assistants, and social work assistants are found under §484.30, §484.32, and §484.34, respectively. We propose to retain these supervision requirements and relocate them under the applicable profession's qualifications and as described in this proposed standard.

We also propose to revise the current personnel qualifications for HHA administrators. Our intent with this provision is to give HHAs flexibility. Therefore, with this provision we would expand the qualifications by which an individual could meet the requirement for an administrator. Specifically, proposed §484.115(a) would set forth the requirements that a HHA administrator would be required to be a licensed physician, or hold an undergraduate degree, or be a registered nurse. We also propose that an administrator would have at least 1 year of supervisory or administrative experience in home health care or a related health care program. The possession of an undergraduate degree would be a new option for establishing the qualifications of an administrator that does not exist in the current regulations. We believe that this new option will give HHAs additional flexibility in selecting an appropriate administrator. However, we do not believe it is necessary to specify which undergraduate degree would be necessary to qualify for this option. Rather, we propose that the HHA's governing body would specify which undergraduate degree an HHA administrator would have to possess. In the absence of state requirements, we are not proposing to add financial management training as a requirement

for HHA administrators at this time since HHAs often employ or consult a chief financial officer and billing staff, and the provision may place an additional burden on current HHAs. We specifically ask for comments on this proposal.

At §484.105(a), the governing body would be responsible for appointing a qualified administrator, subject to the proposed requirements at §484.115(a). If the governing body believed additional qualifications were required for an administrator, it could include these in its hiring criteria.

At §484.115(k) and (l), we propose to retain the current requirements for both social work assistants and social workers, respectively. Currently, a qualified social worker is an individual who has a master's degree in social work (MSW) from an accredited school of social work and who has 1 year of social work experience in a health care setting. A qualified social work assistant is currently a person who has a baccalaureate degree in social work, psychology, sociology, or other field related to social work, and who has at least 1 year of social work experience in a health care setting. A social work assistant is also considered to be qualified under the current home health CoPs if he or she has 2 years of appropriate experience as a social work assistant and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service. However, determinations of proficiency do not apply with respect to persons initially licensed by a state or seeking initial qualification as a social work assistant after December 31, 1977. We believe that these current personnel requirements adequately meet the needs of HHA patients. We propose to clarify the requirement for a social worker by amending the regulation to state that those who hold a doctoral degree in social work would

also meet the qualification requirements.

Finally, we propose to revise the personnel qualifications for speech-language pathologists (SLP) in order to more closely align the regulatory requirements with those set forth in section 1861(ll) of the Act. We propose that a qualified SLP is an individual who has a master's or doctoral degree in speech-language pathology, and who is licensed as a speech-language pathologist by the State in which he or she furnishes such services. To the extent of our knowledge, all states license SLPs; therefore all SLPs would be covered by this option. We believe that deferring to the states to establish specific SLP requirements would allow all appropriate SLPs to provide services to beneficiaries. Should a state choose to not offer licensure at some point in the future, we propose a second, more specific, option for qualification. In that circumstance, we would require that a SLP has successfully completed 350 clock hours of supervised clinical practicum (or is in the process of accumulating supervised clinical experience); performed not less than nine months of supervised full-time speech-language pathology services after obtaining a master's or doctoral degree in speech-language pathology or a related field; and successfully completed a national examination in speech-language pathology approved by the Secretary. These specific requirements are set forth in the Act, and we believe that they are appropriate for inclusion in the regulations as well.

IV. Home Health Crosswalk (Cross reference of current to proposed requirements)

The table below shows the relationship between the current sections to the proposed

Current CoPs	Revised CoPs
§484.1, Basis and scope	Revised at §484.1

§484.2, Definitions	Revised at §484.2
§484.4, Personnel qualifications	Revised at §484.115
Home health aide qualifications	Revised at §484.80
§484.10, Patient rights	**§484.50, Patient rights**
484.10(a)	Revised at §484.50(a)
484.10(b)	Revised at §§484.50(b), (c), and (e)
484.10(c)	Revised at §484.50 (c)
484.10(d)	Revised at §484.50(c)
484.10(e)	Revised at §484.50(c)
484.10(f)	Revised at §484.50(c)
	New standard at §484.50(d), Transfer and discharge
	New standard at §484.50(e), Investigation of complaints
§484.11, Release of patient identifiable OASIS information	**§484.40, Release of patient identifiable outcome and assessment information set (OASIS) information**
§484.12, Compliance with Federal, State, and local laws, disclosure and ownership information, and accepted professional standards and principles	**§484.100, Compliance with Federal, State, and local laws and regulations related to the health and safety of patients**
484.12(a)	Revised at §484.100 and §484.100(b)
484.12(b)	Redesignated at §484.100(a)
484.12(c)	Revised at §484.60, §484.70, and §484.105(f)
§484.14, Organization, services, and administration	**§484.105, Organization and administration of services**
484.14(a)	Revised at §484.105(f)
484.14(b)	Revised at §484.105(a)
484.14(c)	Revised at §484.105(b)
484.14(d)	Revised at §484.75(d), §484.105(b), and §484.105(c)
484.14(e)	Revised at §484.75(b) and §484.115
484.14(f)	Revised at §484.105(e)
484.14(g)	Revised at §484.60(d) and §484.105(c)
484.14(h)	Revised at §484.105(e)
484.14(i)	Revised at §484.105(h)
484.14(j)	Revised at §484.100(c)
§484.16, Group of professional personnel	**Deleted, see §484.65, Quality assessment and performance improvement (QAPI)**
§484.18, Acceptance of patients, plan of care, and medical supervision	**§484.60, Care planning, coordination of services, and quality of care**
484.18(a)	Revised at §484.60(a)

484.18(b)	Revised at §484.60(c)
484.18(c)	Revised at §484.60(b)
§484.20, Reporting OASIS information	**§484.45, Reporting OASIS information**
§484.30, Skilled nursing services	**§484.75, Skilled professional services**
§484.32, Therapy services	**§484.75, Skilled professional services**
§484.34, Medical social services	**§484.75, Skilled professional services**
§484.36, Home health aide services	**§484.80, Home health aide services**
484.36(a)(1)	Revised at §484.80(b)
484.36(a)(2)(i)	Revised at §484.80(f)
484.36(a)(2)(ii)	Revised at §484.80(e)
484.36(a)(3)	Revised at §484.80(b)
484.36(b)(1)	Revised at §484.80(c)
484.36(b)(2)(i)	Revised at §484.80(c)
484.36(b)(2)(ii)	Revised at §484.80(h)
484.36(b)(2)(iii)	Revised at §484.80(d)
484.36(b)(3)(i)	Revised at §484.80(c) and (d)
484.36(b)(3)(ii)	Revised at §484.80(c) and (d)
484.36(b)(3)(iii)	Revised at §484.80(c)
484.36(b)(4)	Revised at §484.80(c)
484.36(b)(5)	Redesignated at §484.80(c)
484.36(b)(6)	Deleted
484.36(c)	Revised at §484.80(g)
484.36(d)	Revised at §484.80(h)
484.36(e)	Revised at §484.80(i)
§484.38, Qualifying to furnish outpatient physical therapy or speech pathology services	Revised at §484.105(g)
§484.48, Clinical records	**§484.110, Clinical records**
484.48(a)	Revised at §484.110(c)
484.48(b)	Revised at §484.110(d)
	New standard at §484.110(a), Contents of clinical record
	New standard at §484.110(b), Authentication
	New standard at §484.110(e), Retrieval of clinical records
§484.52, Evaluation of the agency's program	**Deleted, see §484.65, Quality assessment and performance improvement and §484.70, Infection prevention and control**
§484.55, Comprehensive assessment of patients	**§484.55, Comprehensive assessment of patients**

V. Collection of Information Requirements

Under the Paperwork Reduction Act of 1995 (PRA), we are required to provide 60-day notice in the **Federal Register** and solicit public comment before a collection of information requirement is submitted to the Office of Management and Budget (OMB) for review and approval. In order to fairly evaluate whether an information collection should be approved by OMB, section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995 requires that we solicit comment on the following issues:

- The need for the information collection and its usefulness in carrying out the proper functions of our agency.
- The accuracy of our estimate of the information collection burden.
- The quality, utility, and clarity of the information to be collected.
- Recommendations to minimize the information collection burden on the affected public, including automated collection techniques.

We are soliciting public comment on each of these issues for the following sections of this document that contain information collection requirements (ICRs).

Assumptions and Estimates

We have made several assumptions and estimates in order to assess both the time that it would take for a HHA to comply with the new provisions as well as the costs associated with that compliance. We have detailed these assumptions and estimates in Table 1, and have used these assumptions as the basis for both the Collection of Information and the Regulatory Impact Analysis sections of this rule.

TABLE 1.—ASSUMPTIONS AND ESTIMATES USED THROUGHOUT THE INFORMATION COLLECTION AND IMPACT ANALYSIS SECTIONS

Number of Medicare participating HHAs nationwide	11,930
Number of Medicare participating HHAs that are accredited	5,000
Number of HHA patients in Medicare participating HHAs nationwide	17,751,840
Number of HHA patients in Medicare participating, accredited HHAs	7,440,000
Number of Medicare beneficiaries in HHAs	3,489,201
Average number of new HHAs per year	549
Average number of new, non-accredited HHAs per year	65
Average number of patients per HHA per year	1,488
Hourly rate of registered nurse*	$63
Hourly rate of HHA office employee*	$26
Hourly rate of administrator*	$98
Hourly rate of home health aide*	$20
Hourly rate of clinical manager*	$85
Hourly rate of QAPI coordinator*	$63
Hourly rate of physician*	$180
Hourly rate of therapist (average of PT, OT, SLP)*	$144
Hourly rate of clinician (average of Nurse, Aide, Therapist)*	$76

*Estimate from the Bureau of Labor Statistics Occupational Outlook Handbook, 2014-2015 edition; includes 100 percent benefit and overhead package
** Based on a registered nurse fulfilling this role

Collection of Information Requirements -- Discussion and Summary

A. ICRs Regarding Condition of Participation: Reporting OASIS Information (§484.45)

Proposed §484.45 states that HHAs must electronically report all OASIS data in accordance with §484.55. Specifically, an HHA would have to encode and electronically transmit each completed OASIS assessment to the state agency or the CMS OASIS contractor within 30 days of completing an assessment of a beneficiary. The burden associated with this requirement is the time and effort necessary to conduct the OASIS assessment on a beneficiary and encode and transmit the information to the State agency or the CMS OASIS contractor. While this requirement is subject to the PRA, the burden is currently approved under the following OMB control number, 0938-0760.

B. ICRs Regarding Condition of Participation: Patient Rights (§484.50)

Proposed §484.50 would implement the patient rights provisions of section 1891(a)(1) of the Act, which are currently specified in §484.10. The purpose is to recognize certain rights that home health patients are entitled to, and protect their rights. HHAs would be required to inform each patient of their rights. In proposed §484.50, we would require HHAs to inform patients about the expected outcomes of treatment and the factors that could affect treatment. The HHAs are asked to devote efforts to improve patient's health literacy which lead to an increased comprehension of diagnosis and treatment for both patients and family. Increased comprehension allows patients to remain active and make the best possible decisions for their medical care. The requirements currently specified in §484.10, that are retained in the proposed rule include:

- A HHA must provide the patient and representative with an oral and a written notice of the patient's rights in advance of furnishing care to the patient in a manner that the individual can understand. The HHA must also document that it has

complied with the requirements of this section.

- A HHA must document the existence and resolution of complaints about the care furnished by the HHA that were made by the patient, representative, and family.
- A HHA must advise the patient in advance of the disciplines that will furnish care, the plan of care, expected outcomes, factors that could affect treatment, and any changes in the care to be furnished.
- A HHA must advise the patient of the HHA's policies and procedures regarding the disclosure of patient records.
- A HHA must advise the patient of his or her liability for payment.
- A HHA must advise the patient of the number, purpose, and hours of operation of the state home health hotline.

In addition to the retained requirements, we propose that HHAs must also advise the patient of the following:

- The names, addresses, and telephone numbers of pertinent State and local consumer information, consumer protection, and advocacy agencies.
- The right to access auxiliary aids and language services, and how to access these services.

We foresee that HHAs will develop a standard notice of rights to fulfill the requirements contained in §484.50(a). A copy of the signed notice would serve as documentation of compliance. We estimate that a home health agency will utilize an administrator to develop the patient rights form. All newly established HHAs would need to develop a notice of patient rights document. In order to speed up the process of

becoming Medicare-approved, the majority of new HHAs are choosing to become accredited by a national accrediting organization for Medicare deeming purposes. The patient rights standards and patient notification requirements of the national accrediting organizations would meet or exceed those proposed in this rule; therefore this rule would not impose a burden upon those new HHAs that choose to obtain accreditation status for Medicare deeming purposes. We estimate that it would take 8 hours for each new non-accredited home health agency to develop the form. The total annual burden for new HHAs is 520 hours (8 hours per HHA x 65 HHAs). The estimated cost associated with this requirement is $784 per HHA and $50,960 for all new non-accredited HHAs, annually. In addition, we estimate that it would take each existing HHA 1 hour to update its existing patient rights form, for a one-time total of 11,930 hours and a cost of $1,169,140.

The burden associated with §484.50(e) would be the time and effort necessary to document a patient complaint and its resolution. We estimate that, in a 1 year period, a HHA would need to document complaints involving about 5 percent (74) of its patients. We estimate that the documentation would require 5 minutes per investigation. Accredited HHAs are already required by their accrediting bodies to adhere to stringent patient rights violation investigation and record-keeping standards; therefore accredited HHAs would not be burdened by this new standard. The total annual burden per non-accredited HHA (6,930) would be 6 hours (74 investigations x 5 minutes per investigation/ 60).

We believe that the requirements of proposed standard (f), “Accessibility,” related to providing information to patients in a manner that can be understood would not impose a burden because HHAs are already required to comply with these requirements in

accordance with Title VI of the Civil Rights Act of 1964, the Americans With Disabilities Act, and Section 504 of the Rehabilitation Act. HHAs should already be in compliance with these longstanding requirements.

C. ICRs Regarding Condition of Participation: Comprehensive Assessment of Patients (§484.55)

Proposed §484.55 would require the HHA to conduct, document and update, within a defined timeframe, a patient-specific comprehensive assessment that identifies the patient's need for HHA care and services, and the patient's need for physical, psychosocial, emotional and spiritual care. While these requirements are subject to the PRA, the associated burden imposed by these requirements is considered to be usual and customary medical practice as defined in 5 CFR 1320.3(b)(2). All health care providers, regardless of their type of service, location, or other factors, routinely assess patients to determine their current status and care needs in keeping with the basic tenets of medical care as well as discipline-specific licensure requirements.

D. ICRs Regarding Condition of Participation: Care Planning, Coordination of Services, and Quality of Care (§484.60)

The proposed requirements in this section would reflect an interdisciplinary, coordinated approach to home health care delivery. Proposed §484.60 would require that each patient's written plan of care specify the care and services necessary to meet the patient specific needs identified in the comprehensive assessment. Additionally, the written plan of care would be required to contain the measurable outcomes that the HHA anticipates will occur as a result of implementing and coordinating the plan of care. This

new section incorporates several of the current requirements under §484.18. Section 484.18 consists of longstanding requirements that implement statutory provisions found in sections 1835, 1814, and 1891(a) of the Act. While these requirements are subject to the PRA, the associated collection is currently approved under OMB control number 0938-0365.

Proposed §484.60(a) would require that each patient's written plan of care be established and periodically reviewed by a doctor of medicine, osteopathy, or podiatry. While HHAs average 1,488 home health patient admissions per year, 292 of those are Medicare patients. Having a doctor of medicine, osteopathy, or podiatry establish and periodically review the HHA plan of care is also a requirement for Medicare payment; therefore HHAs would do this in the absence of this proposed requirement. Thus this requirement would not impose a burden for those 292 Medicare patients per HHA. The anticipated burden associated with this requirement involves a member of the office support staff who would facilitate interaction with the physician. We estimate that this would take 5 minutes per admission for a total estimated burden of 100 hours per HHA ([1196 non-Medicare admits per year x 5 minutes] / 60 minutes per hour).

Proposed §484.60(a)(4) and (b)(1) would require HHAs to conform and fulfill all medical orders issued in writing or telephone (and later authenticated) by a patient's physician or qualified medical professional. While this requirement is subject to the PRA, we believe that this is usual and customary medical practice and therefore does not add additional burden as specified in 5 CFR 1320.3(b)(2). Issuing orders for patient care is one of the most fundamental tasks performed by physicians. Likewise, documenting and

adhering to physician orders is one of the most fundamental tasks performed by the physician and all other clinicians within a patient's health care team, including the nurses, therapists, and social workers that are involved in home health care.

Proposed §484.60(c) would require an HHA to review, revise and document the plan on a timely basis. The burden associated with these requirements is the time and effort associated with reviewing, revising, and maintaining the plan of care. This requirement is currently approved under OMB control number 0938-0365.

Proposed §484.60(e) would require a HHA to develop a discharge summary for each patient upon his or her discharge. The standard would describe the necessary elements of the discharge summary, but would not require a specific form to be used. The current HHA requirements at §484.48, Clinical records, already requires HHAs to develop and file a discharge summary for each discharged patient. Therefore, we believe that developing a discharge summary is a usual and customary HHA practice and does not add additional burden.

E. ICRs Regarding Condition of Participation: Quality Assessment and Performance Improvement (QAPI) (§484.65)

Proposed §484.65 would require HHAs to develop, implement, maintain and evaluate an effective, data driven quality assessment and performance improvement program. Current requirements for HHAs do not provide for the operation of an internal quality assessment and performance improvement program, whereby the HHA examines its methods and practices of providing care, identifies the opportunities to improve its performance and then takes actions that result in higher quality of care for HHA patients.

We have not prescribed the structures and methods for implementing this requirement and have focused the condition toward the expected results of the program. This provides flexibility to the HHA, as it is free to develop a creative program that meets the HHA's needs and reflects the scope of its services. This new provision would replace the current conditions at §484.16, "Group of professional personnel," and §484.52, "Evaluation of an agency's program."

The first standard under §484.65 requires that a HHA's quality assessment and performance improvement program must include, but not be limited to, the use of objective measures to demonstrate improved performance. The second standard requires the HHA to track its performance to assure that improvements are sustained over time. The third standard requires that the HHA must set priorities for performance improvement, consider prevalence and severity of identified problems, and give priority to improvement activities that affect clinical outcomes. Lastly, the fourth standard requires the HHA to participate in periodic, external quality improvement reporting requirements as may be specified by CMS.

We believe the writing of internal policies governing the HHA's approach to the development, implementation, maintenance, and evaluation of the quality assessment and performance improvement program, as described in §484.65, will impose a new burden. We want HHAs to utilize maximum flexibility in their approach to quality assessment and performance improvement programs. Flexibility is provided to HHAs to ensure that each program reflects the scope of its services. We believe that this requirement provides a performance expectation that HHAs will set their own QAPI plan and goals and use the

information to continuously strive to improve their performance over time. Given the variability across HHAs and the flexibility provided, we believe that the burden associated with writing the internal policies governing the approach to the development, implementation, and evaluation of the quality assessment and performance improvement program will reflect that diversity. We estimate that the burden associated with writing the internal policies would be an average of 4 hours annually per HHA, for an industry-wide total of 27,720 hours. (4 hours per HHA x 6,930 non-accredited HHAs), and an industry-wide cost of $1,746,360 (27,720 hours x $63/hour).

Although there are other QAPI requirements, they do not relate to record keeping and, therefore, are not relevant to this section.

F. ICRs Regarding Condition of Participation: Infection Prevention and Control (§484.70)

Proposed §484.70 would require and HHA to maintain and document an infection control program with the goal of preventing and controlling infections and communicable diseases. Specifically, proposed §484.70(b) would state that the HHA must maintain a coordinated agency-wide program for the surveillance, identification, prevention, control, and investigation of infectious and communicable diseases that is an integral part of the HHA's QAPI program. Proposed §484.70(c) would also require that each HHA provide infection control education to staff, patients, and caregivers. We believe the associated burden for documenting the infection prevention and control program is exempt as stated in 5 CFR 1320.3(b)(2). Since health care-acquired infections have been a source of significant research, education, and training efforts by both the public and private health care sectors for more than a decade, maintaining documents and disclosing information

pertaining to infection control is generally regarded as a usual and customary business practice in the HHA community.

G. ICRs Regarding Condition of Participation: Skilled Professional Services (§484.75)

We propose to consolidate current provisions governing skilled nursing services at §484.30, therapy services at §484.32, and medical social services at §484.34, under one new condition, §484.75. Rather than having separate CoPs for each discipline, we would, in a single CoP, broadly describe the expectations for all skilled professionals who participate in the interdisciplinary approach to home health care delivery. Proposed §484.75 would require skilled professionals who provide services to HHA patients as employees or under arrangement to participate in all aspects of care. This includes, but is not limited to, participation in the on-going patient assessment process; development and maintenance of the interdisciplinary plan of care; patient, caregiver, and family counseling; patient and caregiver education; and communication with other health care providers. Proposed §484.75 would also require skilled professionals to be actively involved in the HHA's QAPI program and participate in HHA in-service trainings. Furthermore, proposed §484.75 would require skilled professional services to be supervised. Clinician involvement in patient care, quality improvement efforts, and continuing education are all commonly accepted as good medical practice and typically part of state licensure requirements. The supervision of clinician services is also standard medical practice to ensure that patient care is delivered in a safe and effective manner. In addition, the aforementioned requirements would in all likelihood exist in the absence of federal regulations, thereby exempting the associated burden as stated in 5 CFR 1320.3(b)(3).

H. ICRs Regarding Condition of Participation: Home Health Aide Services (§484.80)

This section governs the requirements for home health aide services. Many requirements in this section directly mirror the statutory requirements of sections 1891 and 1861 of the Act and include the following requirements: (1) The HHA must maintain sufficient documentation to demonstrate that training requirements are met; (2) The HHA's competency evaluation must address all required subjects; (3) The HHA must maintain documentation that demonstrates that requirements of competency evaluation are met; and (4) a registered nurse or appropriate skilled professional prepares written instructions for care to be provided by the home health aide.

In this rule we propose to retain, for the most part, the requirements at current §484.36, but place them in a new condition of participation at §484.80. We would also add the provisions from §484.4 concerning the qualifications for home health aides. All home health aide services must be provided by individuals who meet the personnel requirements and training criteria as specified. A HHA is required to maintain documentation that each home health aide meets these qualifications as specified in proposed §484.80(a). The burden associated with these standards is the time required to document that each new aide meets the qualification requirements. We estimate that it will take 5 minutes per newly hired home health aide per year to document the information. We assume that the average home health agency would replace 30 percent of its home health aides in a given year, or roughly two home health aides a year based an average of six home health aide FTEs (Basic Statistics About Home Care Updated 2010, National Association for Home Care, http://www.nahc.org/facts/10HC_Stats.pdf). Based on an estimate of 5 minutes per newly

hired aide and two newly hired aides per agency, per year, we estimate that there will be 1,988 annual burden hours ([5 minutes per aide x 2 aides per HHA] / 60 minutes per hour x 11,930 HHAs) for the home health industry. We assume that an office employee ($26/hour) would perform this function at a cost of $4 per HHA per year. The total cost for all HHAs is $51,688 (1,988 hours x $26/hour).

Proposed §484.80(b)(1) through (3) would discuss the content and duration of the home health aide classroom and supervised practical training. With respect to the recordkeeping requirements, proposed §484.80(b)(4) states that an HHA would be required to maintain documentation that demonstrates that the requirements of this standard have been met. The burden associated with this requirement would be the time and effort necessary to document the information and maintain the documentation as part of the HHAs records. We estimate that it would take each of the 11,930 HHAs 5 minutes per newly hired aide per year to document that the requirements of this standard have been met. The estimated annual burden is 1,988 hours ([5 minutes per aide x 2 aides per HHA]/ 60 minutes per hour x 11,930 HHAs). The cost burden associated with this requirement is $51,688, based on an office employee completing the documentation ($26/hour x 1,988 hours).

Proposed §484.80(c) contains the standard for competency evaluation. An individual could furnish home health services on behalf of an HHA only after that individual has successfully completed a competency evaluation program as described in this section. With respect to the recordkeeping requirements, proposed §484.80(c)(5) states that an HHA would be required to maintain documentation that demonstrates that the

requirements of this standard have been met. The burden associated with this requirement would be the time and effort necessary to document the information and maintain the documentation as part of the HHAs records. We estimate that it would take each of the 11,930 HHAs 5 minutes per newly hired aide per year to document that the requirements of this standard have been met. The estimated annual burden is 1,988 hours ([5 minutes per aide x 2 aides per HHA]/ 60 minutes per hour x 11,930 HHAs). The cost burden associated with this requirement is $51,688, based on an office worker completing the documentation ($26/hour x 1,988 hours).

Proposed §484.80(d) states that a home health agency would be required to maintain documentation that all home health aides have received at least 12 hours of in-service training during each 12-month period. The burden associated with this requirement would be the time and effort necessary to document and maintain records of the required in-service training. We assume that it would require 5 minutes per aide to document the in-service training, and that these trainings would be conducted on a quarterly basis, for a total of 2 hours per HHA, annually, to meet this requirement ([5 minutes per aide per training x 4 trainings per year x 6 aides]/60 minutes per hour). The estimate total annual burden for this requirement is 23,860 hours (2 hours per HHA x 11,930 HHAs).

Proposed §484.80(g) would state that written patient care instructions for a home health aide must be prepared by a registered nurse or other appropriate skilled professional who is responsible for the supervision of a home health aide. The burden associated with this requirement would be the time and effort necessary for a registered nurse or other

skilled professional to draft written patient care instructions for a home health aide. Providing written patient care instructions is a usual and customary medical practice, and is therefore exempt from the PRA under 5 CFR 1320.3(b)(2). Home health aide licensure standards require aides to practice under the direction of a nurse or other qualified medical professional. Likewise, the scope of practice for nurses and other qualified medical professionals includes the preparation of patient care instructions.

This proposed rule at §484.80(h) would also require HHAs to document the supervision of home health aides in accordance with specified timeframes. Supervising employees to ensure the safe and effective provision of patient care is standard business practice throughout the health care community. Likewise, documenting that this supervision has occurred for internal personnel, accreditation, and state and federal compliance purposes is standard practice and thereby exempt from the PRA under 5 CFR 1320.3(b)(2).

I. ICRs Regarding Condition of Participation: Compliance with Federal, State, and Local Laws and Regulations Related to the Health and Safety of Patients (§484.100)

Provisions concerning compliance with federal state, and local laws are currently located at §484.12, "Compliance with Federal, State and local laws, disclosure of ownership information and accepted professional standards and principles." We propose to retain most of the provisions contained in this condition with minor changes, which are discussed below. Under the proposed reorganization scheme, discussed above, this condition would be set forth at §484.100.

As stated in proposed §484.100(a), the HHA would be required to disclose to the

state survey agency at the time of the HHA's initial request for certification the name and address of all persons with an ownership or control interest in the HHA, the name and address of all officers, directors, agents, and managers of the HHA, as well as the name and address of the corporation or association responsible for the management of the HHA and the chief executive and chairman of that corporation or association. This requirement directly implements section 1891 of the Act. This provision expands upon a similar requirement currently contained in §405.1221(b). It would impose a minimal burden of adding the necessary additional information to the current disclosure used by HHAs as required by current §484.12(b), which further reference the requirements of 42 CFR part 420, subpart C related to Medicare Program Integrity requirements. We estimate that modifying the current disclosure would require 5 minutes per HHA, for a total of 994 hours for the HHA industry as a whole on a one-time basis ([5 minutes per modification x 11,930 existing agencies] / 60 minutes per hour). Additionally, we estimate that it would require new HHAs 1 hour to develop a disclosure statement, for a total of 549 annual hours industry wide each year (1 hour per new HHA x 549 new HHAs).

J. ICRs Regarding Condition of Participation: Organization and Administration of Services (§484.105)

This proposed section would set forth the organization and administration of services provided by a HHA. It would state that the HHA must organize, manage, and administer its resources to attain and maintain the highest practicable functional capacity for each patient regarding medical, nursing, and rehabilitative needs as indicated by the plan of care. The revised organization and administration of services condition would

simplify the structure of the current requirements, and provide flexibility to the HHA by reducing the current focus on organizational structures and focusing on new performance expectations for the administration of the HHA as an organizational entity. Although there are reporting and documentation requirements associated with the proposed requirements, these activities are standard business practice and would not impose a burden on HHAs. For example, proposed §484.105(d)(1) would state that the parent HHA is responsible for reporting all branch locations of the HHA to the state survey agency at the time of the HHA's request for initial certification, at each survey, and at the time the parent proposes to add or delete a branch. Similarly, proposed §484.105(e)(2) would state that an HHA must have a written agreement with another agency, with an organization, or with an individual when that entity or individual furnishes services under arrangement to the HHA's patients. We believe the burden associated with the aforementioned actions is exempt from the PRA under 5 CFR 1320.3(b)(2).

Paragraph (h) of this section, Institutional planning, would impose a minimal burden of the time required by new HHAs to develop the initial plan and by existing HHAs to review and revise the existing plan. We estimate the burden for developing a new plan at 1½ hours (90 minutes) and the burden for reviewing and revising an existing plan at 30 minutes. Accredited HHAs are required by their accrediting bodies to engage in institutional planning efforts that exceed these proposed minimum federal requirements; therefore this requirement would not impose a burden upon accredited agencies. In addition, the vast majority of new HHAs are entering the Medicare program via accreditation from a national accrediting body; therefore this provision would not be

imposing a burden upon new agencies as well. The estimated annual burden for existing HHAs is 3,465 hours ([6,930 existing non-accredited HHAs x 30 minutes] / 60 minutes per hour). The estimated annual burden for anticipated new HHAs is 98 hours (1.5 hours per HHA x 65 new HHAs).

K. ICRs Regarding Condition of Participation: Clinical Records (§484.110)

This section would set forth the requirements that clinical records contain pertinent past and current findings, and are maintained for every patient who is accepted by the HHA for home health services. A clinical record containing pertinent past and current findings would be maintained for every patient receiving home health services. All entries in the clinical record would be authenticated, dated and timed, which is usual and customary clinical practice and does not impose a burden. Clinical records would be retained for 5 years after the month the cost report for the records is filed with the intermediary. HHAs would be required to have written procedures that govern the use and removal of records, and the conditions for release of information. This section contains longstanding provisions that are specifically required in section 1861(o) of the Act, and are necessary to preserve the patient's privacy and the quality of care. While these requirements are subject to the PRA, we believe the associated burden is exempt as stated in 5 CFR 1320.3(b)(2). The aforementioned documentation and record retention requirements are considered usual and customary business practices and impose no additional burden.

At §484.110(a)(5) we propose to require a HHA to send a copy of a patient's discharge summary to the patient's primary care practitioner or other health care professional who will be responsible for providing care and services to the patient after

discharge from the HHA, or the facility, if the patient leaves HHA care to enter a facility for further treatment. We estimate that a HHA would spend 5 minutes per patient sending the discharge summary to the patient's next source of health care services, for a total of 124 hours per average HHA annually ([5 minutes per patient x 1,488 patients] / 60 minutes per hour) at a cost of $3,224 for an office employee to send the required documentation ($26 per hour x 124 hours). Complying with this provision would require 1,479,320 hours (124 hours per HHA x 11,930 HHAs) and $38,462,320 ($3,224 per HHA x 11,930 HHAs) for all HHAs, annually.

Furthermore, a home health agency must make clinical records, whether in hard copy or electronic form, readily available on request by an appropriately authorized individual or entity. The burden associated with this requirement is the time and effort required to disclose a clinical record to an appropriate authority. While this requirement is subject to the PRA, we believe the associated burden is exempt as stated in 5 CFR 1320.3(b)(2). Making clinical records available to the appropriate authority is part of the survey and certification process, and imposes no additional burden as a usual and customary business practice.

L. ICRs Regarding Personnel Qualifications (§484.115)

In §484.115, we defer to state certification or state licensure requirements in cases where personnel requirements are not statutory or do not relate to a specific payment provision. As defined in 5 CFR 1320.3(b)(2), these requirements are usual and customary business practices. As defined in 5 CFR 1320.3(b)(3), a state requirement would exist even in the absence of the federal requirement. The associated burden is thereby exempt.

Table 2: Burden and Cost Estimates Associated with Information Collection Requirements

Regulation Section	OMB Control No.	Respondents	Responses	Burden per Response (in hours)	Total Annual Burden (in hours)	Hourly Labor Cost of Reporting ($)	Total Cost of Reporting ($)	Total Costs ($)
*§484.50(a)	0938-New	65	65	8	520*	98	50,960	50,960
*§484.50(a)	0938-New	11,930	11,930	1	11,930*	98	1,169,140	1,169,140
§484.50(e)	0938-New	6,930	512,820	0.083	42,735	63	2,692,305	2,692,305
§484.60(a)		11,930	14,268,280	0.083	1,189,023	26	36,914,598	36,914,598
*§484.65(e)	0938-New	6,930	6,930	4	27,720*	63	1,746,360	1,746,360
§484.80(a)	0938-New	11,930	23,860	0.083	1,988	26	51,688	51,688
§484.80(b)	0938-New	11,930	23,860	0.083	1,988	26	51,688	51,688
§484.80(c)	0938-New	11,930	23,860	0.083	1,988	26	51,688	51,688
§484.80(d)	0938-New	11,930	286,320	0.083	23,860	26	620,360	620,360
§484.100(a)	0938-New	11,930	11,930	0.083	994	98	97,412	97,412
*§484.100(a) §484.105(h)	0938-New	549 6,930	549 6,930	1 0.5	549* 3,465	98 98	53,802 339,570	53,802 339,570
§484.105(h)		65	65	1.5	98	98	9,604	9,604
§484.110(a)	0938-New	11,930	17,751,840	0.083	1,479,320	26	38,462,320	38,462,320
Total		**19,474**	**32,929,239**		**2,786,178**		**82,311,495**	**82,311,495**

* Denotes a one-time information collection requirement.

There are no capital/maintenance costs associated with the information collection requirements contained in this rule; therefore, we have removed the associated column from Table 2. In addition, the column for the total costs is also represents the total cost of reporting; therefore, we have removed the total cost of reporting column from Table 2 as well.

If you comment on these information collection and recordkeeping requirements, please do either of the following:

1. Submit your comments electronically as specified in the ADDRESSES section of this proposed rule; or

2. Submit your comments to the Office of Information and Regulatory Affairs, Office of Management and Budget,

Attention: CMS Desk Officer, CMS-3819-P

Fax: (202) 395-6974; or

Email: OIRA_submission@omb.eop.gov

VI. Regulatory Impact Analysis

A. Introduction

We have examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96-354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104-4), Executive Order 13132 on Federalism (August 4, 1999) and the Congressional Review Act (5 U.S.C. 804(2).

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). A regulatory impact analysis (RIA) must be prepared for major rules with economically significant effects ($100 million or more in any 1 year).

This rule is a proposed revision of the Medicare and Medicaid CoPs for HHAs. The CoPs are the basic health and safety requirements that an HHA must meet in order to receive payment from the Medicare and Medicaid programs. This proposed rule would incorporate advances and current medical practices in caring for home health patients while removing unnecessary process and procedure requirements contained in the current CoPs. This is a major rule because the overall economic impact for all of the proposed new CoPs

is estimated to be $148 million in year 1 and $142 million in year 2 and thereafter.

B. Statement of Need

As the single largest payer for health care services in the United States, the Federal Government assumes a critical responsibility for the delivery and quality of care furnished under its programs. Historically, we have adopted a quality assurance approach that has been directed toward identifying health care providers that furnish poor quality care or fail to meet minimum federal standards, but this problem-focused approach has inherent limits. Ensuring quality through the enforcement of prescriptive health and safety standards, rather than improving the quality of care for all patients, has resulted in our expending much of our resources on dealing with marginal providers, rather than on stimulating broad-based improvements in the quality of care delivered to all patients.

This proposed rule would adopt a new approach that focuses on the care delivered to patients by home health agencies while allowing HHAs greater flexibility and eliminating unnecessary procedural requirements. As a result, we are proposing to revise the HHA requirements to focus on a patient-centered, data-driven, outcome-oriented process that promotes high quality patient care at all times for all patients. We have developed a proposed set of fundamental requirements for HHA services that would encompass patient rights, comprehensive patient assessment, and patient care planning and coordination by an interdisciplinary team. Overarching these requirements would be a QAPI program that would build on the philosophy that a provider's own quality management system is key to improved patient care performance.

These proposed regulations contain two critical improvements that would support

and extend our focus on patient-centered, outcome-oriented surveys. First, the proposed regulations are designed to enable surveyors to look at outcomes of care, because the regulations would specify that each individual receive the care which his or her assessed needs demonstrate is necessary, rather than focusing simply on the services and processes that must be in place. Second, the addition of a strong QAPI requirement would not only stimulate the HHA to continuously monitor its performance and find opportunities for improvement, it would also afford the surveyor the ability to assess how effectively the provider was pursuing a continuous quality improvement agenda. All of the changes would be directed toward improving patient-centered outcomes of care. We believe that the overall approach of the proposed CoPs would increase performance expectations for HHAs, in terms of achieving needed and desired outcomes for patients and increasing patient satisfaction with services provided.

C. Summary of Impacts

Section V of this rule, Collection of Information Requirements, provides a detailed analysis of the burden hours and associated costs for all burdens related to the collection of information by HHAs that would be required by this proposed rule. That section, in tandem with this regulatory impact analysis section, present a full account of the burdens that would be imposed by this rule. Because the burdens have already been assessed in the Collection of Information Requirements section, we will not recount them in this RIA section. In addition to analyzing the burden hours and associated costs for all burdens related to these proposed requirements, we have also assessed the potential savings associated with our proposal to remove certain outdated, burdensome requirements that

exist in the current HHA CoPs. All estimates presented in this RIA section are based on the assumptions presented in Table 1, located at the beginning of the Section V of this rule, Collection of Information Requirements.

Table 3: Summary of estimated burden for all proposed CoPs

CoP	**Total Time**	**Total Cost in Year 1**	**Annual Cost in Year 2 and Thereafter**
Burden and Cost Estimates Associated with Information Collection Requirements	2,786,178 hours	$82,311,495	$79,291,233
Patient rights	2,349,960 hours	$144,074,520	$144,074,520
QAPI	561,330 hours	$26,403,300	$22,993,740
Infection prevention and control	540,540 hours	$34,054,020	$34,054,020
Removal of 60 day summary requirement	-887,592 hours	-$16,864,248	-$16,864,248
Removal of Group of professional personnel requirement	-192,868 hours	-$19,422,040	-$19,422,04012
Removal of Evaluation of the agency's program	-1,359,953 hours	-$102,305,699	-$102,305,699
TOTAL	**3,797,595hours**	**$148,251,348**	**$141,821,526**

D. Detailed Economic Analysis

1. Burden Assessment

Reporting OASIS information (Proposed §484.45)

We propose only one change to this current CoP at §484.45(c)(3). In this standard we propose to replace the requirement that an HHA have a direct telephone connection to transmit the OASIS data with a requirement at §484.45(c) that an HHA transmit data using electronic communications software that complies with the Federal Information Processing Standard (FIPS 140-2, issued May 25, 2001) from the HHA or the HHA contractor to the

CMS collection site. The FIPS 140-2 applies to all Federal agencies that use cryptographic-based security systems to protect sensitive information in computer and telecommunication systems (including voice systems) as defined in Section 5131 of the Information Technology Management Reform Act of 1996, Public Law 104-106, including CMS. Therefore, this proposed requirement does not impose a new burden upon HHAs.

Patient rights (Proposed §484.50)

The proposed rule would require that an agency would have to provide a patient and a patient's representative (if any) with a written notice of rights. Communicating with patients and representatives, including the provision of a written notice of rights, is a standard practice in the health care industry and would impose no additional costs. Similar requirements already exist for many other health care provider types, including hospice providers, long term care facilities, ambulatory surgery centers, and end-stage renal disease facilities.

Verbal notification of rights in a language and manner that the individual understands, however, may create a new burden for some HHAs. The national accrediting organizations already require their accredited HHAs to orally apprise their patients of their rights in situations where patients cannot read or understand the written notice. We assume, for purposes of this analysis only, that accredited HHAs are providing oral notification to the 25 percent of their patients that cannot read or understand the written notice. Based on this assumption, 1,860,000 patients are already orally notified of their rights each year; therefore, we are excluding these patients from this analysis. For the remaining 75 percent of patients receiving care from an accredited HHA, we estimate that

it would take approximately five minutes per patient to describe the content of the notice of rights and obtain the patient's signature confirming that he or she has received a copy of the notice. We assume that patients would be informed of their rights by a registered nurse at a cost of $5 per patient (5 minutes x $63/hour). The total number of hours per accredited HHA would be 93 hours (1,116 patients x 5 minutes per patient / 60 minutes), at a cost of $5,580 (1,116 patients x $5 per patient).

For non-accredited HHAs, the requirement to provide this verbal notice would be a new requirement for all 1,488 patients served in an average HHA each year. The total cost of this provision per non-accredited HHA would be $7,440 (1,488 patients x $5 per patient). The total number of hours per non-accredited HHA would be 124 hours (1,488 patients x 5 minutes per patient / 60 minutes). The total cost for all HHAs would be $79,459,200 ([$7,440 per non-accredited x 6,930 HHAs] + [$5,580 per accredited HHA x 5,000 HHAs]). The total number of hours for all HHAs would be 1,324,320 hours ([124 hours per non-accredited HHA x 6,930 HHAs] + [93 hours per non-accredited HHA x 5,000 HHAs]).

We note that the requirement to communicate with patients in a language and manner that the patient understands is not a new expectation for Medicare-approved HHAs, as they are already required to be in compliance with the current civil rights requirements and guidance (see 42 CFR 489.10(b)). Specifically, HHAs are already required to comply with the requirements of Title VI of the Civil Rights Act of 1954, Section 504 of the Rehabilitation Act of 1973, the Age Discrimination Act of 1975, and "other pertinent requirements of the Office of Civil Rights of HHS." HHS guidance, issued in 2003, further

explains the expected role of translators in communications with patients ("Guidance to Federal Assistance Recipients Regarding Title VI Prohibition Against National Origin Discrimination Affecting Limited English Proficient Persons," August 8, 2003, 68 FR 47311). As such, the proposed requirement to communicate with patients in a language and manner that the patient understands would not impose a new burden on HHAs.

Proposed §484.50(e) would require that all patient/family complaints be investigated. We estimate that, in a one year period, a HHA would need to investigate complaints involving about 5 percent (74) of its patients, and that each investigation would take 2 hours to complete. The total annual burden per HHA would be 148 hours (74 investigations x 2 hour per investigation). All national accrediting organizations already require their accredited HHAs to document, investigate, and resolve patient complaints; therefore all 5,000 accredited HHAs would not be burdened by this proposed requirement. The total annual burden hours for the industry would be 1,025,640 (148 hours per HHA x 6,930 non-accredited HHAs). The total annual cost for the QAPI coordinator to complete all investigations would be $9,324 per HHA ($63/hour x 148 hours), and $64,615,320 for all non-accredited HHAs ($46/hour x 1,025,640 hours).

Table 4: Patient Rights

Standard	**Time per HHA**	**Total time**	**Cost per HHA**	**Total cost**
Providing notice of rights (annual, non-accredited/accredited HHAs)	124/93 hours	1,324,320 hours	$7,440/5,580	$79,459,200
Investigations (annual, non-accredited HHAs)	148 hours	1,025,640 hours	$ 9,324	$64,615,320
TOTAL (annual, non-accredited/accredited**)**	**272 or 93 hours**	**2,349,960 hours**	**$16,764 or $5,580**	**$144,074,520**

Comprehensive assessment of patients (Proposed §484.55)

We propose to retain the requirements of current §484.55, with a reorganization of several sections related to the content of the comprehensive assessment and the addition of several broad focus areas. We believe that the new focus areas (for example, cognitive status and patient goals) are standard practice and would not impose an additional burden. In addition, we propose a minor change to allow for the completion of an OASIS update upon the physician-ordered resumption of care date. Allowing for a physician to order the resumption of care date increases HHA flexibility; therefore there is no new burden associated with this retention.

Care planning, coordination of services, and quality of care (Proposed §484.60)

The current regulations at §484.12(c), "Compliance with accepted professional standards and principles"; §484.14(g), "Coordination of patient services"; and §484.18 "Acceptance of patients, plan of care, and medical supervision," would be reorganized and revised at proposed §484.60.

The change in §484.18, "Acceptance of patients, plan of care, and medical supervision," would require HHAs to provide each patient with a written copy of the plan of care, including any additions or revisions. The plan of care would include all orders, would specify the care and services necessary to meet the patient-specific needs and the measurable outcomes that the HHA anticipates would occur as a result of implementing and coordinating the plan of care with the patient and physician, and would include all patient and caregiver education and training specific to the patient's needs. The intent of the current standard at §484.12(c) would be retained under this proposed CoP with the

requirement that services be furnished in accordance with accepted standards of practice. No burden is associated with this part of the proposed CoP, as these requirements constitute current industry practices regarding plans of care.

Proposed §484.60(a), "Plan of care," would codify current industry standards of practice through the revision of current §484.18(a), "Plan of care," including references to the identification of patient-specific needs and measurable outcomes that are already currently required under current §484.55, "Comprehensive assessment of patients." Therefore, this proposed requirement would not present a new burden.

Proposed §484.60(b), "Conformance with physician orders," would retain the provision of the current regulation at 42 CFR 484.18(c) that allows HHAs to administer influenza and pneumococcal vaccinations without specific physician orders, provided that certain requirements are adhered to. As an allowance of flexibility, rather than an imposition of a specific requirement, we believe that this provision would not impose a burden upon HHAs.

This proposed standard also retains many of the current requirements regarding verbal orders with the exception of the proposed requirement at §484.60(b)(5), "Conformance with physician orders," which would require the physician to countersign and date all verbal orders. Although this requirement is not in the current regulations, this and similar physician order practices are consistent with current standards of practice and with many state laws. Therefore, we expect no new burden with this proposal.

Proposed §484.60(c), "Review and revision of the plan of care," would incorporate some current requirements. Although there has been some revision to current §484.18(b),

"Periodic review of plan of care," to include mention of measurable outcomes for patients, the intent of this proposed requirement already exists at §484.55, "Comprehensive assessment of patients." Section 484.55 requires an HHA to demonstrate patient progress toward the achievement of desired outcomes. Therefore, the current standard remains essentially intact in this proposed rule and the new standard would not constitute any new burden.

Proposed §484.60(d), "Coordination of care," would revise current §484.14(g), "Coordination of patient services," and some elements of current §484.18(a), "Plan of care." The intent of the current standards remains intact, and these revisions do not generate new burden.

Quality assessment and performance improvement (QAPI) (Proposed §484.65)

The quality assessment and performance improvement (QAPI) requirement replaces the current quality-related requirements of §484.16, "Group of professional personnel," and §484.52, "Evaluation of the agency's program." Quality assessment is already part of standard HHA practice through annual evaluations of an agency's total program using both administrative reviews and a quarterly review of a sample of clinical records. Furthermore, HHAs are already familiar with the basic concept of measuring quality on both a patient and aggregate level. This rule would further refine current HHA quality efforts and bring HHA quality programs in line with their counterparts in a variety of other settings, such as hospitals and hospices. Likewise, this rule would bring non-accredited HHA quality practices in line with those of their accredited counterparts. The national accrediting organizations have spent a decade or more enhancing, expanding, and refining their

quality-related standards, and those standards far exceed the current Medicare regulations. Indeed, the current quality-related standards established by the accrediting organizations would, we believe, even exceed those that we propose to require in this rule. Since accredited HHAs would already have QAPI programs that meet the requirements of this rule by virtue of meeting the already existing accreditation standards, we are not including accredited HHAs in our analysis of the impact of this requirement. This rule would provide a basic outline of what QAPI is and how we expect it to function in the HHA environment. Each HHA would be free to decide how to implement the QAPI requirement in a manner that reflects its own unique needs and goals.

For purposes of this impact analysis we have described the impact in three general phases that we believe an average HHA will go through. These phases are based on our experience in implementing the QAPI requirements in hospices, another home-based provider type with a similar operating structure and patient population. While we have outlined these phases below, we stress that an HHA would not be required to approach QAPI in this manner. The QAPI requirement would not stipulate that an HHA must collect data for a specific domain; use specific quality measures, policies and procedures, or forms; submit QAPI data to an outside body; or conduct a specified number of performance improvement projects. An HHA may choose to implement a data-driven, comprehensive QAPI program that meets the requirements of this rule in any way that meets its individual needs. These phases described below simply provide a framework for assessing the potential impact of the QAPI requirement upon an average non-accredited HHA.

In phase one, we believe that an HHA would:

- Identify quality domains and measurements that reflect its organizational complexity; involve all HHA services; affect patient outcomes, patient safety, and quality of care; focus on high risk, high volume, or problem-prone areas; and track adverse patient events;
- Develop and revise policies and procedures to ensure that data is consistently collected, documented, retrieved, and analyzed in an accurate manner; and
- Educate HHA employees and contractors about the QAPI requirement, philosophy, policies, and procedures.

In phase two, we believe that a HHA would:

- Enter data into patient clinical records during patient assessments;
- Aggregate data by collecting the same pieces of data from patient clinical records and other sources (for example, human resource records);
- Analyze the data that is aggregated through charts, graphs, and various other methods to identify patterns, anomalies, areas of concern, etc. that may be useful in targeting areas for improvement; and
- Develop, implement, and evaluate major and minor performance improvement projects based on a thorough analysis of the data collected.

In phase three, we believe that a HHA would:

- Identify new domains and measures that may replace or be in addition to the domains and measures already being monitored by the HHA;
- Develop and/or revise policies and procedures to accommodate the new domains and measures; and

- Educate HHA employees and contractors on the new domains and measures, as well as the policies and procedures for them.

In addition to these three phases, an HHA would likely allocate resources to an individual responsible for the general overall coordination of its QAPI program. For simplicity, we refer to this individual as the QAPI coordinator; however, a HHA is not required to use this title. For purposes of this analysis only, we assume that a HHA would choose a QAPI coordinator who has a clinical background, such as a nurse.

Based on these three phases, we have anticipated the impact of the QAPI requirement on a HHA's resources. In phase one, we anticipate that an HHA would use 9 hours to identify quality domains and measures. HHA quality domains and measures are readily available. Indeed, HHAs already collect data for a wide variety of domains and measures each year as part of the OASIS patient assessment data collection tool, and this data is already used to calculate quality measures as presented in OBQI, OBQM, and PBQI reports and the home health compare website. These sources provide a robust starting point for HHAs in the quality measurement efforts. We expect that these hours would be distributed among the three members of the HHA's QAPI committee. While we do not require an HHA to have a QAPI committee, we believe that most HHAs would choose to do so to ensure a variety of perspectives are represented in the QAPI decision-making process. We believe that the QAPI committee would include the QAPI coordinator, the HHA administrator, and a clinical manager. We estimate that the QAPI committee would meet three times per year for 1 hour each meeting to identify appropriate quality domains and measures. We estimate that, in total, the QAPI committee would need 9 hours

annually to identify appropriate quality domains and measures (3 staff hours per meeting x 3 meetings per year). The total annual cost for an average HHA to identify the domains and measures is $738 ($189 per QAPI coordinator + $294 per administrator + $255 per clinical manager). The total cost for all HHAs is $5,114,340 ($738 per HHA x 6,930 non-accredited HHAs).

In addition to selecting measures and developing policies and procedures for QAPI activities, we anticipate that HHAs would train appropriate staff in data collection for any new data elements necessary to calculate quality measures, as well as the overall QAPI philosophy and efforts within the agency. For purposes of this analysis, we assume HHAs would train all clinical staff in the basic concept of QAPI, the agency's implementation of this requirement, and any agency-specific policies and procedures. We estimate that an HHA would spend 1 hour per staff member to provide this training, as many staff are already familiar with data collection and its role in quality measurement and improvement through the OASIS, OBQI, and PBQI instruments. For purposes of our analysis we are including patient care clinicians because they are the staff that are most likely to be performing data collection. In 2009, Medicare- certified HHAs had 242,020 clinician FTEs, for an average of 24 clinical FTEs per HHA. The cost per HHA is $1,824. (1 hour per clinical staff member x 24 clinical staff members x $76 per hour per clinical staff member) The total hour for non-accredited HHAs is 166,320 (24 hours per average HHA x 6,930 non-accredited HHAs) and the total cost is $12,640,320 (166,320 hours x $76/hour).

Phase two is related to gathering, entering, and analyzing data for quality assessment and performance improvement purposes. Thoroughly assessing a patient and

collecting patient data in a standardized manner is already standard practice due to the OASIS regulations. The presence of the OASIS data set and quality reporting measures has been in place for several years and the concepts of each are fully integrated into standard HHA practices. Therefore, we do not believe that it would be a burden for HHAs to incorporate new data gathered for dual patient care planning and QAPI purposes into their current systems and processes.

We believe that any additional burden would arise from the act of entering, aggregating, and analyzing other types of available data that HHAs already collect for other purposes (for example, staffing productivity, staff vacancy rates, timeliness of delivery of services). We estimate that, in order to ensure that the volume of gathered data was manageable, a HHA would have to gather its data once a month. A HHA could choose to gather data on a more or less frequent basis to suit its needs and circumstances. Some HHAs may choose to gather all patient-level data, but we believe that most HHAs would choose to gather data from a sample of clinical records. Likewise, some HHAs could choose to gather data from a wide variety of administrative files, while others may choose to select only a few administrative data sources. There are many combinations that a HHA may choose to use when it comes to gathering data, and no single approach is considered preferable to another. Given this variability, it is difficult to estimate how long an average HHA may spend gathering and organizing data. For purposes of this analysis only, we assume that an average HHA would use 4 hours per month to gather data, for a total of 48 hours a year. We believe that an office employee would perform the data aggregation and organization at a cost of $1,248 (4 hours x 12 months x $26/hour) per HHA. The total cost

is $8,648,640 ($1,248 per HHA x 6,930 HHAs). Following data gathering and organization, a HHA would have to analyze the data to identify trends, patterns, anomalies, areas of strength and concern. We believe that this data analysis would be done by the QAPI committee described previously. In order to identify trends and patterns, the committee would need to examine several months of data at the same time. Therefore, we assume that the committee would meet once every quarter to examine the data and make decisions based on the analysis. Meeting to discuss quality measure data is standard practice in the HHA industry. HHAs are well versed in quality measure reports due to the OBQI and new PBQI reports produced by CMS and the quality measure reports available to the public on the Home Health Compare website. Since HHAs already meet to discuss and analyze quality measure results, we do not believe that this requirement would impose a new burden.

Performance improvement projects follow all of the data entry, gathering, organization, and analysis. A HHA would have to conduct projects to improve its performance in areas where a weakness was identified. Performance improvement projects would have to reflect the HHA's scope, complexity, and past performance. They would also have to be data-driven, and affect patient outcomes, patient safety, and quality of care. Although this rule would more clearly describe a performance improvement project, its basis, and its purpose, it is based on the same concept as the current requirement at §484.52, "Evaluation of the agency's program," which requires that results of the evaluation are reported and acted upon by those responsible for the operation of the agency. Since a HHA already takes action to ensure that its program is appropriate, adequate,

effective, and efficient, and since providing safe and effective care at all times for all patients is the essential charge of all health care providers, we believe that conducting both major and minor performance improvement projects is already a standard of practice within the HHA industry. Therefore, there would be no additional burden associated with this provision. Although we do not believe that the requirement to conduct performance improvement projects will require additional time and resources, we do believe that the required focus of such projects, and their data-driven nature, will help HHAs improve the efficiency and effectiveness that they achieve in these projects. We believe that such improved project efficiency and effectiveness may result in improved patient outcomes, avoidance of future adverse events, more appropriate resource allocation, and a wide variety of other beneficial outcomes, based on the projects selected by each HHA.

Phase three of the QAPI process builds upon the QAPI program that a HHA already has in place. We estimate that a HHA would use 3 hours a year to identify new domains and quality measures, and we believe that the QAPI committee would perform this task, at a total cost of $246 (1 hour x $63/hour for QAPI coordinator + 1 hour x $98/ hour for administrator + 1 hour x $85/hour rate for clinical manager). The total annual cost for non-accredited HHAs in updating domain and measures is $1,704,780 ($246 per HHA x 6,930 HHAs) in year 2 and thereafter.

Table 5: Quality assessment and performance improvement

Standard	Time per HHA	Total time	Cost per HHA	Total cost
Identify domains and measures(1st year)	9 hours	62,370 hours	$738	$5,114,340
Train staff (1st year and on-going)	24 hours	166,320 hours	$1,824	$12,640,320
Aggregate data (1st year	48 hours	332,640 hours	$1,248	$8,648,640

and on-going)				
Update domains and measures (on-going)	3 hours	20,790 hours	$246	$1,704,780
TOTAL 1st year	**81 hours**	**561,330 hours**	**$3,810**	**$26,403,300**
TOTAL yearly on-going	**75hours**	**519,750 hours**	**$3,318**	**$22,993,740**

Infection prevention and control (Proposed §484.70)

There is no specific current requirement addressing infection control in the current HHA CoPs. However, current §484.12(c), "Compliance with accepted professional standards and principles," requires a HHA and its staff to comply with accepted professional standards and principles that apply to professionals furnishing services in an HHA. Given this broad requirement, we believe that HHA personnel are already using well-documented infection control practices and well-accepted professional standards and principles in their patient care practices. This proposed regulation would reinforce positive infection control practices and would address the serious nature, as well as the potential hazards, of infectious and communicable diseases in the home health environment. This rule would also bring non-accredited HHA quality practices in line with those of their accredited counterparts. The national accrediting organizations have spent a decade or more developing and refining their infection prevention and control standards in the absence of specific Medicare regulations. Indeed, the current infection prevention and control standards established by the accrediting organizations would, we believe, even exceed those that we propose to require in this rule.

Specifically, the regulation would require HHAs to have an organized, agency-wide program for the surveillance, identification, prevention, control, and investigation of

infectious and communicable diseases that is an integral part of the HHA's quality assessment and performance improvement (QAPI) program. The agency's program would be required to include the following:

- The use of accepted standards of practice, including standard precautions, to prevent the transmission of infections and communicable diseases;
- A method for identifying infectious and communicable disease problems;
- A plan for the appropriate actions that are expected to result in improvement and disease prevention; and
- Education to staff, patients, and caregivers about infection prevention and control issued and practices.

We believe that developing this organized program would require HHA resources, and estimate that an HHA would use 1.5 hours of staff time each week, or 78 hours per year (1.5 hours x 52 weeks), to develop and maintain the infection prevention and control program. At a cost of $63 per hour for a nurse to provide program leadership, the cost would be $4,914 per HHA (78 hours x $63/hour)

While we cannot quantify the benefits of having an organized program for the prevention and control of infections, we believe that such a program would produce benefits for HHAs and their patients. For example, such a program may improve the manner in which HHAs identify to HHA staff those patients who are infected or colonized with antibiotic resistant bacteria so that staff may take additional precautions in order to protect themselves during interactions with patients, thereby reducing the amount of sick leave used by HHA staff, thus increasing staff productivity. We do not have adequate data

from which to create accurate estimates of the potential benefits of this proposed requirement, but we believe that they are substantial.

Table 6: Infection prevention and control

Standard	Time per HHA	Total time	Cost per HHA	Total cost
Develop and maintain program	78 hours	540,540 hours	$4,914	$34,054,020
TOTAL	**78 hours**	**540,540 hours**	**$4,914**	**$34,054,020**

Skilled professional services (Proposed §484.75)

We would consolidate current provisions located at §484.30, "Skilled nursing services"; §484.32, "Therapy services"; and §484.34, "Medical social services," into this new requirement. We would add a requirement that skilled professionals participate in the QAPI program. Involvement in patient care and patient care-related activities is a professional responsibility, and therefore we believe involvement in the agency's QAPI program would impose little or no additional burden. We would also add a requirement, somewhat similar to the requirement at §484.14(d), regarding the supervision of nursing assistants, therapy assistants, and medical social service assistants. We would require that all nursing services be provided under the supervision of a registered nurse; all rehabilitative therapy assistant services be provided under the supervision of a physical therapist or occupational therapist; and all medical social services be provided under the supervision of a social worker. These supervision requirements codify current HHA supervision practices, and therefore would not impose a new burden upon HHAs.

Home health aide services (Proposed §484.80)

Home health aide services are an integral part of home health care, and the

proposed CoP retains many of the current longstanding requirements. However, in an effort to make the current requirements for home health aides more consistent throughout, improve overall clarity, and reflect current standards of practice more accurately, we have reorganized and revised the requirements in this proposed CoP. The burdens associated with this section are described in the Collection of Information section of this rule. Therefore, we are not repeating those burdens in this section. Other proposed changes, such as requiring HHAs to supervise aides when performing skills for which the aides have not passed a competency evaluation or requiring aides to report changes in a patient's condition to a registered nurse or other appropriate skilled professional, constitute standard practice within the HHA industry. Therefore, no new burdens would be imposed by these proposed changes.

Compliance with Federal, State, and local laws and regulations related to health and safety of patients (Proposed §484.100)

The current regulations at §484.12(a), "Compliance with Federal, State, and local laws and regulations"; §484.12(b), "Disclosure of ownership and management information"; and §484.14(j), "Laboratory services," have been reorganized with only minor clarifying revisions to the language of each standard. The current condition statement would also be modified slightly for clarification purposes. However, the current regulation regarding compliance with all applicable laws and regulations related to patient health and safety, state licensing of HHAs, and laboratory services, essentially would remain intact under this proposed rule. The burden associated with this provision would be the disclosure of certain information, which was discussed in the Collection of Information

section of this rule, and there are no other burdens associated with this provision.

Organization and administration of services (Proposed §484.105)

Several of the requirements currently found at §484.14, "Organization, services, and administration," have been reorganized and revised under this proposed condition. As previously discussed in the preamble to this proposed rule, the current standard at §484.14(f), "Personnel under hourly or per visit contracts," would be deleted. Additionally, as we have already discussed above in this section, the standards currently found at §484.14(e), "Personnel policies," §484.14(g), "Coordination of patient services," and §484.14(j), "Laboratory services," would be reorganized with minor revisions under proposed §484.60(d), "Coordination of care," §484.100(c), "Laboratory services," and §484.105(c), "Clinical manager," respectively.

In order to facilitate compliance with §484.60(d) and to ensure that each patient's care is coordinated, we propose to combine, revise, and elaborate on current §484.14(d) and (e) at proposed §484.105(c), "Clinical manager." This standard would require a qualified physician or registered nurse to provide oversight of all patient care services and HHA personnel. Oversight would include making patient and personnel assignments; coordinating patient care; coordinating referrals; assuring the development, implementation, and updates of the individualized plan of care; and developing personnel qualifications. The clinical manager role in the regulations would be a further refinement of the current "Supervising physician or registered nurse" role found in regulation at §418.14(d) and in statute at 1861(o)(2) of the Act; therefore the general duties described above are already required of home health agencies. The complex, multi-disciplinary

nature of home health care necessitates both personnel supervision and patient care coordination to ensure the effective delivery of patient care and positive patient outcomes. The clinical manager position would not constitute any new functions within an HHA; rather, it provides a more structured approach for patient care coordination and personnel supervision tasks. Since the various patient care coordination functions already in existence would be consolidated under the clinical manager position and would thus be a realignment of current resource allocations, we do not believe that this requirement would pose a new burden.

Clinical records (Proposed §484.110)

The current regulation at §484.48, "Clinical records," would be revised, and reorganized under this proposed CoP. We believe that the majority of the revisions to the current clinical record requirement reflect contemporary professional standards already in place in the home health industry. Therefore, no additional burden would be imposed. In addition, the proposed requirements would allow HHAs to maintain and send a patient's clinical record in electronic form. This flexibility may result in a reduction in burden for many HHAs with systems of electronic record keeping already in place.

Personnel qualifications (Proposed §484.115)

We would reorganize the personnel qualification requirements currently found at §484.4, "Personnel qualifications," in a new CoP dedicated to personnel qualification standards. Within this new condition we propose to use the term "licensed practical nurse" instead of the current term of "practical (vocational) nurse" since the former is more commonly used and accepted. We also propose that the possession of any undergraduate

degree would be sufficient for an administrator. In addition, we propose to expand the qualifications for social workers to include those individuals who possess either a master's (M.S.W) or a doctor's degree (D.S.W.) in social work. Furthermore, we propose to defer to state licensure requirements as the basis for determining the qualifications of SLPs. This expansion of the qualifications for administrators, social workers, and SLPs could provide an agency more flexibility in hiring these professions if it chose, and could provide a potential reduction in burden, though we are not able to quantify what this reduction might be at this time. These changes would create no new burden for HHAs.

2. Deleted requirements

We propose to delete three requirements of the current HHA regulations in their entirety. First, we would delete §484.14(g), removing the requirement that an HHA must send a written summary report for each patient to the attending physician every 60 days. This requirement currently imposes a burden of 3 minutes per patient, and 887,592 hours, annually, for all HHAs at a cost of $16,864,248, as indicated by the currently-approved PRA package (OMB control number 0938-0365). Therefore, removing this requirement would save HHAs $16,864,248 each year. We would encourage agencies to assist the patient in seeking physician follow-up during each certification period.

Second, we would delete §484.16, "Group of professional personnel," because the QAPI requirements would address the same goals as are currently required of the group of professional personnel. This requirement currently imposes a documentation burden of 10 minutes per HHA, and 1,988 hours, annually, for all HHAs at a cost of $37,772, as indicated by the currently-approved PRA package (OMB control number 0938-0365).

In addition to the burden related to documentation, we believe that eliminating this requirement would also alleviate the burden of holding meetings with the group of professional personnel for the sole purpose of complying with this regulatory requirement. The regulation requires that the group must consist of at least one physician, one registered nurse, and representation from other professional disciplines, with at least one member who is not employed by or an owner of the HHA. Since the regulations at §484.14(a) require HHAs to provide skilled nursing services as well as the services of at least one other discipline, not including physician services, we know that the group of professional personnel would be required to have at least three members. For purposes of this analysis, we assume that the group of professional personnel would include a physician ($180), a registered nurse ($63/hour), a therapist ($144), and a home health aide ($20). The regulation also requires that the group of professional personnel must meet "frequently." For purposes of this analysis, we assume that the frequency requirement would be met by holding quarterly meetings of the group. Furthermore, we assume that most quarterly meetings would require 1 hour of each member's time, for a total of 4 labor hours per meeting, or 16 labor hours per year per HHA. We estimate the cost associated with this requirement to be $407 per meeting, or $1,628 per HHA per year ($407 per meeting x 4 meetings per year), for a total of 190,880 hours (16 hours per HHA x 11,930 HHAs) at cost of $19,422,040 ($1,628 per HHA x 11,930 HHAs) per year. Therefore we estimate that the total reduction of burden would be 192,868 hours (190,880 hours + 1,988 hours) and $19,459,812($19,422,040 + $37,772).

Third, we would delete §484.52, "Evaluation of the agency's program," because the

prescriptive quarterly review of clinical records is outdated and unnecessary. This requirement currently imposes a documentation burden of 11,863 hours, annually, for all HHAs at a cost of $304,199, as indicated by the currently-approved PRA package (OMB control number 0938-0365).

In addition to the documentation burden imposed by this requirement, we believe that there is a burden associated with the time necessary to complete the quarterly clinical record reviews. The regulation requires that appropriate health professionals, representing at least the scope of the program, review a sample of both active and closed clinical records to determine whether established policies are followed in furnishing services directly or under arrangement. There is a continuing review of clinical records for each 60-day period that a patient receives home health services to determine adequacy of the plan of care and appropriateness of continuation of care. Each professional may review the records separately, at different times. For purposes of this analysis, we assume that a HHA would review a 5 percent sample of its clinical records, or an average of 75 clinical records per year per facility. Furthermore, for purposes of this analysis, we assume that a registered nurse ($63/hour), a therapist ($144/hour), and a home health aide ($20/hour) reviews each clinical record, and that each review would require 30 minutes per discipline, for a total of 90 minutes per record review. We estimate that each HHA uses 113 hours per year to meet this requirement, for a total of 1,348,090 hours for all HHAs. The total cost per record review is $114, or $8,550 per HHA per year, for a total of $102,001,500 for all HHAs. Therefore, we believe that removing this requirement would alleviate a total burden of 1,359,953 hours and $102,305,699.

3. Impact on patient care

Although the positive effects of these proposed changes cannot be quantified, we note that the proposed changes are focused on improving the delivery of care to each and every patient. For example, the proposed QAPI standard would encourage HHAs to use their own internally-generated data to proactively identify patient care inefficiencies, contradictions, lapses, and other issues in the care delivery system so that HHAs can rapidly implement performance improvement projects designed to remedy the issue(s) at hand. Proactively identifying care issues and implementing projects to correct those issues would ultimately lead to more effective and efficient patient care and improved patient outcomes. However, as previously indicated, we cannot quantify the impact on patients.

E. Alternatives Considered

The primary alternative considered for this rule was to not propose any changes to the health home conditions of participation and instead remain with the current regulations. However, in order to continuously improve care that is provided to all patients in the home health setting, CMS has chosen to propose the updates to the current regulations.

If CMS made the decision not to propose these changes, there would be a savings of $142 million, annually, that would not be incurred by home health agencies because they would not be required to change current practices. However, as stated in the impact section of this rule, there is the potential for significant benefits, ranging from improved patient outcomes to increased staff productivity, which may be realized by HHAs as a result of improved practices and a higher quality patient care.

F. Accounting Statement

As required by OMB Circular A-4 (available at http://www.whitehouse.gov/omb/circulars_a004_a-4), we have prepared an accounting statement in Table 7 showing the classification of the transfers and costs associated with the provisions of this proposed rule for CY 2014.

TABLE 7: Accounting Statement: Classification of Estimated Net Costs from FY 2015 to FY 2019 (in millions)

Category	Estimates	Units		
		Year Dollar	Discount Rate	Period Covered
Costs				
Annualized Monetized ($million/year)	138	2014	7%	2015 - 2019
	138	2014	3%	2015 - 2019

Although the benefits of these proposed changes cannot be quantified, we note that the proposed changes are focused on improving the delivery of care to each and every patient. An increased focus on identifying and proactively addressing risk factors for emergency department visits and hospital re-admissions has the potential to reduce both, leading to improved patient health and decreased payer expenditures. Likewise, requiring HHAs to educate and teach patients the necessary self-care skills to facilitate a timely discharge may lead to more and better patient engagement in managing chronic health conditions such as diabetes, ultimately leading to improved patient health and reduced payer expenditures. However, as previously indicated, we cannot quantify the impact on

patients.

G. Regulatory Flexibility Act (RFA)

The RFA requires agencies to analyze options for regulatory relief of small businesses, if a rule has a significant impact on a substantial number of small entities. For purposes of the RFA, small entities include small businesses, nonprofit organizations, and government agencies. Individuals and states are not included in the definition of a small entity. For the purposes of the RFA, most HHAs are considered to be small entities, either by virtue of their nonprofit status or government status, or by having revenues less than $14 million in any 1 year (for details, see the Small Business Administration's (SBA) web site at http://www.sba.gov/sites/default/files/files/size_table_07222013.pdf (refer to the 620000 series). There are 11,930 Medicare-certified HHAs with average annual patient census of 1,488 patients per HHA. An average Medicare-participating HHA in 2010 had annual revenues (all payment sources) of $6.55 million. Therefore, the vast majority of these Medicare-certified HHAs would be considered small entities under the SBA's NAICS.

As its measure of significant economic impact on a substantial number of small entities, HHS uses a change in revenue of more than 3 to 5 percent. We do not believe that this threshold will be reached by the requirements in this proposed rule because the cost of this rule on a per-HHA basis is minimal (approximately a $20,500 net increase in burden per non-accredited HHA in the first year, and a small net savings of approximately $100 for accredited HHAs in the first year). Therefore, we certify that this rule would not have a significant economic impact on a substantial number of small entities.

In addition, section 1102(b) of the Act requires us to prepare a regulatory impact

analysis if a rule may have a significant impact on the operations of a substantial number of small rural hospitals. This analysis must conform to the provisions of section 603 of the RFA. For purposes of section 1102(b) of the Act, we define a small rural hospital as a hospital that is located outside of a metropolitan statistical area and has fewer than 100 beds. We believe that this rule would not have a significant impact on the operations of a substantial number of small rural hospitals because there are few HHAs in those facilities.

H. Unfunded Mandates Reform Act (UMRA)

Section 202 of the Unfunded Mandates Reform Act of 1995 (UMRA) also requires that agencies assess anticipated costs and benefits before issuing any rule whose mandates require spending in any 1 year of $100 million in 1995 dollars, updated annually for inflation. In 2014, that threshold is approximately $141 million. It includes no mandates on state, local, or tribal governments. The estimates presented in this section of the proposed rule exceed this threshold and, as a result, we have provided a detailed assessment of the anticipated costs and benefits in RIA section as well as other parts of the preamble

I. Federalism

Executive Order 13132 establishes certain requirements that an agency must meet when it promulgates a proposed rule (and subsequent final rule) that imposes substantial direct requirement costs on state and local governments, preempts state law, or otherwise has Federalism implications. This rule has no Federalism implications.

J. Congressional Review Act

This proposed regulation is subject to the Congressional Review Act provisions of

the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 et seq.) and has been transmitted to the Congress and the Comptroller General for review.

In accordance with the provisions of Executive Order 12866, this proposed rule was reviewed by the Office of Management and Budget.

List of Subjects

42 CFR Part 409

Health facilities, Medicare.

42 CFR Part 410

Health facilities, Health professions, Kidney diseases, Laboratories, Medicare, Reporting and recordkeeping requirements, Rural areas, X-rays.

42 CFR Part 418

Health facilities, Hospice care, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 440

Grant programs-health, Medicaid.

42 CFR Part 484

Health facilities, Health professions, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 485

Grant programs-health, Health facilities, Medicaid, Medicare, Reporting and recordkeeping requirements.

42 CFR Part 488

Administrative practice and procedure, Health facilities, Medicare, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, the Centers for Medicare & Medicaid Services proposes to amend 42 CFR Chapter IV as set forth below:

PART 409 -- HOSPITAL INSURANCE BENEFITS

1. The authority citation for part 409 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

PART 410 -- SUPPLEMENTARY MEDICAL INSURANCE (SMI) BENEFITS

2. The authority citation for part 410 continues to read as follows:

Authority: Secs. 1102, 1834, 1871, 1881, and 1893 of the Social Security Act (42 U.S.C. 1302. 1395m, 1395hh, and 1395ddd.

PART 418 -- HOSPICE CARE

3. The authority citation for part 418 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

PART 440 – SERVICES: GENERAL PROVISIONS

4. The authority citation for part 440 continues to read as follows:

Authority: Sec. 1102 of the Social Security Act (42 U.S.C. 1302).

5. In the table below, for each section and paragraph indicated in the first two columns, remove the reference indicated in the third column and add the reference indicated in the fourth column:

Section	**Paragraphs**	**Remove**	**Add**
§409.43	(a)	§484.18(a)	§484.60(a)

§409.43	(c)(1)(i)(C)	42 CFR 484.4	42 CFR 484.115
§409.43	(d)	§484.4	§484.115
§409.44	(b)(1) introductory text and (c)(2)(ii)	§484.4	§484.115
§409.45	(c)(4)	§484.4	§484.115
§409.46	(b)	§484.36(d)	§484.80(h)
§409.47	(b)	§484.14(h)	§484.105(e)
§410.62	(a) introductory text	§484.4	§484.115
§418.76	(f)(1)	§484.36(a) and §484.36 (b)	§484.80
§418.76	(f)(2)	§484.36(a)	§484.80(a)
§440.110	(a)(2) and (b)(2)	§484.4	§484.115 of this chapter

PART 484 -- HOME HEALTH SERVICES

6. The authority citation for part 484 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395(hh)) unless otherwise indicated.

7. Part 484 is amended by revising subparts A through C to read as follows:

Subpart A--General Provisions

Sec.

484.1 Basis and scope.

484.2 Definitions.

Subpart B--Patient Care

484.40 Condition of participation: Release of patient identifiable outcome and assessment information set (OASIS) information.

484.45 Condition of participation: Reporting OASIS information.

484.50 Condition of participation: Patient rights.

484.55 Condition of participation: Comprehensive assessment of patients.

484.60 Condition of participation: Care planning, coordination of services, and quality of care.

484.65 Condition of participation: Quality assessment and performance improvement (QAPI).

484.70 Condition of participation: Infection prevention and control.

484.75 Condition of participation: Skilled professional services.

484.80 Condition of participation: Home health aide services.

Subpart C--Organizational Environment

484.100 Condition of participation: Compliance with Federal, State, and local laws and regulations related to health and safety of patients.

484.105 Condition of participation: Organization and administration of services.

484.110 Condition of participation: Clinical records.

484.115 Condition of participation: Personnel qualifications.

Subpart A--General Provisions

§484.1 Basis and scope.

(a) Basis. This part is based on:

(1) Sections 1861(o) and 1891 of the Act, which establish the conditions that an HHA must meet in order to participate in the Medicare program and which, along with the additional requirements set forth in this part, are considered necessary to ensure the health and safety of patients; and

(2) Section 1861(z), which specifies the institutional planning standards that HHAs must meet.

(b) Scope. The provisions of this part serve as the basis for survey activities for the purpose of determining whether an agency meets the requirements for participation in the Medicare program.

§484.2 Definitions.

As used in subparts A, B, and C, of this part--

Branch office means an approved location or site from which a home health agency provides services within a portion of the total geographic area served by the parent agency. The parent home health agency must provide supervision and administrative control of any branch office. It is unnecessary for the branch office to independently meet the conditions of participation as a home health agency.

Clinical note means a notation of a contact with a patient that is written, timed, and dated, and which describes signs and symptoms, treatment, drugs administered and the patient's reaction or response, and any changes in physical or emotional condition during a given period of time.

In advance means that HHA staff must complete the task prior to performing any hands-on care or any patient education.

Parent home health agency means the agency that provides direct support and administrative control of a branch.

Primary home health agency means the HHA which accepts the initial referral of a patient, and which provides services directly to the patient or via another health care

provider under arrangements (as applicable).

Proprietary agency means a private, for-profit agency.

Public agency means an agency operated by a state or local government.

Quality indicator means a specific, valid, and reliable measure of access, care outcomes, or satisfaction, or a measure of a process of care.

Representative means the patient's legal guardian or other person who participates in making decisions related to the patient's care or well-being, including but not limited to, a person chosen by the patient, a family member, or an advocate for the patient. The patient determines the role of the representative, to the extent possible.

Subdivision means a component of a multi-function health agency, such as the home care department of a hospital or the nursing division of a health department, which independently meets the conditions of participation for HHAs. A subdivision that has branch offices is considered a parent agency.

Summary report means the compilation of the pertinent factors of a patient's clinical notes that is submitted to the patient's physician.

Supervised practical training means training in a practicum laboratory or other setting in which the trainee demonstrates knowledge while providing covered services to an individual under the direct supervision of either a registered nurse or a licensed practical nurse who is under the supervision of a registered nurse.

Verbal Order means a physician order that is spoken to appropriate personnel and later put in writing for the purposes of documenting as well as establishing or revising the patient's plan of care.

Subpart B--Patient Care

§484.40 Condition of participation: Release of patient identifiable outcome and assessment information set (OASIS) information.

The HHA and agent acting on behalf of the HHA in accordance with a written contract must ensure the confidentiality of all patient identifiable information contained in the clinical record, including OASIS data, and may not release patient identifiable OASIS information to the public.

§484.45 Condition of participation: Reporting OASIS information.

HHAs must electronically report all OASIS data collected in accordance with §484.55.

(a) Standard: Encoding and transmitting OASIS data. An HHA must encode and electronically transmit each completed OASIS assessment to the CMS system, regarding each beneficiary with respect to which information is required to be transmitted (as determined by the Secretary), within 30 days of completing the assessment of the beneficiary.

(b) Standard: Accuracy of encoded OASIS data. The encoded OASIS data must accurately reflect the patient's status at the time of assessment.

(c) Standard: Transmittal of OASIS data. An HHA must—

(1) For all completed assessments, transmit OASIS data in a format that meets the requirements of paragraph (d) of this section.

(2) Successfully transmit test data to the state agency or CMS OASIS contractor.

(3) Transmit data using electronic communications software that complies with the Federal Information Processing Standard (FIPS 140-2, issued May 25, 2001) from the HHA or the HHA contractor to the CMS collection site.

(4) Transmit data that includes the CMS-assigned branch identification number, as applicable.

(d) Standard: Data format. The HHA must encode and transmit data using the software available from CMS or software that conforms to CMS standard electronic record layout, edit specifications, and data dictionary, and that includes the required OASIS data set.

§484.50 Condition of participation: Patient rights.

The patient and representative (if any), have the right to be informed of the patient's rights in a language and manner the individual understands. The HHA must protect and promote the exercise of these rights.

(a) Standard: Notice of rights. The HHA must--

(1) Provide the patient and the patient's representative (if any), the following information during the initial evaluation visit, in advance of furnishing care to the patient:

(i) Written notice of the patient's rights and responsibilities under this rule. Written notice must be understandable to persons who have limited English proficiency and accessible to individuals with disabilities; and

(ii) Verbal notice of the patient's rights and responsibilities in the individual's primary or preferred language and in a manner the individual understands, free of charge, with the use of a competent interpreter if necessary.

(2) Provide contact information for the HHA administrator, including the administrator's name, business address, and business phone number in order to receive complaints or questions.

(3) Provide the OASIS privacy notice to all patients for whom the OASIS data is collected.

(4) Obtain the patient's or representative's signature confirming that he or she has received a copy of the notice of rights and responsibilities.

(b) Standard: Exercise of rights. (1) If a patient has been adjudged incompetent under state law by a court of proper jurisdiction, the rights of the patient may be exercised by the person appointed by the state court to act on the patient's behalf.

(2) If a state court has not adjudged a patient incompetent, the patient's representative may exercise the patient's rights.

(3) If a patient has been adjudged to lack legal capacity under state law by a court of proper jurisdiction, the patient may exercise his or her rights to the extent allowed by court order.

(c) Standard: Rights of the patient. The patient has the right to—

(1) Have his or her property and person treated with respect;

(2) Be free from verbal, mental, sexual, and physical abuse, including injuries of unknown source, neglect and misappropriation of property;

(3) Make complaints to the HHA regarding treatment or care that is (or fails to be) furnished, and the lack of respect for property and/or person by anyone who is furnishing services on behalf of the HHA;

(4) Participate in, be informed about, and consent or refuse care in advance of and during treatment, where appropriate, with respect to--

(i) Completion of the comprehensive assessment;

(ii) The care to be furnished, based on the comprehensive assessment;

(iii) Establishing and revising the plan of care, including receiving a copy of it;

(iv) The disciplines that will furnish the care;

(v) The frequency of visits;

(vi) Expected outcomes of care, including patient-identified goals, and anticipated risks and benefits;

(vii) Any factors that could impact treatment effectiveness; and

(viii) Any changes in the care to be furnished.

(5) Receive all services outlined in the plan of care.

(6) Have a confidential clinical record. Access to or release of patient information and clinical records is permitted in accordance with 45 CFR parts 160 and 164.

(7) Be advised of --

(i) The extent to which payment for HHA services may be expected from Medicare, Medicaid, or any other Federally-funded or Federal aid program known to the HHA,

(ii) The charges for services that may not be covered by Medicare, Medicaid, or any other Federally-funded or Federal aid program known to the HHA,

(iii) The charges the individual may have to pay before care is initiated; and

(iv) Any changes in the information provided in accordance with paragraph (c)(7) of this section when they occur. The HHA must advise the patient and representative (if

any), of these changes as soon as possible, in advance of the next home health visit. The HHA must comply with the patient notice requirements at 42 CFR 411.408(d)(2) and (f).

(8) Receive proper written notice, in advance of a specific service being furnished, if the HHA believes that the service may be non-covered care; or in advance of the HHA reducing or terminating on-going care. The HHA must also comply with the requirements of 42 CFR 405.1200 through 405.1204.

(9) Be advised of the state toll free home health telephone hot line, its contact information, its hours of operation, and that its purpose is to receive complaints or questions about local HHAs.

(10) Be advised of the names, addresses, and telephone numbers of pertinent, Federally-funded and State-funded, State and local consumer information, consumer protection, and advocacy agencies.

(11) Be free from any discrimination or reprisal for exercising his or her rights or for voicing grievances to the HHA or an outside entity.

(12) Be informed of the right to access auxiliary aids and language services as described in paragraph (f) of this section, and how to access these services.

(d) Standard: Transfer and discharge. The patient and representative (if any), have a right to be informed of the HHA's policies for admission, transfer, and discharge in advance of care being furnished. The HHA may only transfer or discharge the patient from the HHA if:

(1) The transfer or discharge is necessary for the patient's welfare because the HHA and the physician who is responsible for the home health plan of care agree that the HHA

can no longer meet the patient's needs, based on the patient's acuity. The HHA must ensure a safe and appropriate transfer to other care entities when the needs of the patient exceed the HHA's capabilities;

(2) The patient or payer will no longer pay for the services provided by the HHA;

(3) The transfer or discharge is appropriate because the patient's health and safety have improved or stabilized sufficiently, and the HHA and the physician who is responsible for the home health plan of care agree that the patient no longer needs the HHA's services;

(4) The patient refuses services, or elects to be transferred or discharged;

(5) The HHA determines, under a policy set by the HHA for the purpose of addressing discharge for cause that meets the requirements of paragraphs (d)(5)(i) through (iii) of this section, that the patient's (or other persons in the patient's home) behavior is disruptive, abusive, or uncooperative to the extent that delivery of care to the patient or the ability of the HHA to operate effectively is seriously impaired. The HHA must do the following before it discharges a patient for cause:

(i) Advise the patient, representative (if any), the physician who is responsible for the home health plan of care, and the patient's primary care practitioner or other health care professional who will be responsible for providing care and services to the patient after discharge from the HHA (if any) that a discharge for cause is being considered;

(ii) Make efforts to resolve the problem(s) presented by the patient's behavior, the behavior of other persons in the patient's home, or situation;

(iii) Provide the patient and representative (if any), with contact information for other agencies or providers who may be able to provide care; and

(iv) Document the problem(s) and efforts made to resolve the problem(s), and enter this documentation into its clinical records;

(6) The patient dies; or

(7) The HHA ceases to operate.

(e) Standard: Investigation of complaints. (1) The HHA must—

(i) Investigate complaints made by a patient, the patient's representative (if any), and the patient's caregivers and family regarding the following:

(A) Treatment or care that is (or fails to be) furnished, is furnished inconsistently, or is furnished inappropriately; and

(B) Mistreatment, neglect, or verbal, mental, sexual, and physical abuse, including injuries of unknown source, and/or misappropriation of patient property by anyone furnishing services on behalf of the HHA.

(ii) Document both the existence of the complaint and the resolution of the complaint; and

(iii) Take action to prevent further potential violations while the complaint is being investigated.

(2) Any HHA staff (whether employed directly or under arrangements) in the normal course of providing services to patients, who identifies, notices, or recognizes incidences or circumstances of mistreatment, neglect, verbal, mental, sexual, and/or physical abuse, including injuries of unknown source, or misappropriation of patient property, must report these findings immediately to the HHA and other appropriate authorities.

(f) Standard: Accessibility. Information must be provided to patients in plain language and in a manner that is accessible and timely to—

(1) Persons with disabilities, including accessible web sites and the provision of auxiliary aids and services at no cost to the individual in accordance with the Americans with Disabilities Act and Section 504 of the Rehabilitation Act.

(2) Persons with limited English proficiency through the provision of language services at no cost to the individual, including oral interpretation and written translations.

§484.55 Condition of participation: Comprehensive assessment of patients.

Each patient must receive, and an HHA must provide, a patient-specific, comprehensive assessment. For Medicare beneficiaries, the HHA must verify the patient's eligibility for the Medicare home health benefit including homebound status, both at the time of the initial assessment visit and at the time of the comprehensive assessment.

(a) Standard: Initial assessment visit. (1) A registered nurse must conduct an initial assessment visit to determine the immediate care and support needs of the patient; and, for Medicare patients, to determine eligibility for the Medicare home health benefit, including homebound status. The initial assessment visit must be held either within 48 hours of referral, or within 48 hours of the patient's return home, or on the physician-ordered start of care date.

(2) When rehabilitation therapy service (speech language pathology, physical therapy, or occupational therapy) is the only service ordered by the physician who is responsible for the home health plan of care, and if the need for that service establishes program eligibility, the initial assessment visit may be made by the appropriate

rehabilitation skilled professional.

(b) Standard: Completion of the comprehensive assessment. (1) The comprehensive assessment must be completed in a timely manner, consistent with the patient's immediate needs, but no later than 5 calendar days after the start of care.

(2) Except as provided in paragraph (b)(3) of this section, a registered nurse must complete the comprehensive assessment and for Medicare patients, determine eligibility for the Medicare home health benefit, including homebound status.

(3) When physical therapy, speech-language pathology, or occupational therapy is the only service ordered by the physician, a physical therapist, speech-language pathologist or occupational therapist may complete the comprehensive assessment, and for Medicare patients, determine eligibility for the Medicare home health benefit, including homebound status. The occupational therapist may complete the comprehensive assessment if the need for occupational therapy establishes program eligibility.

(c) Standard: Content of the comprehensive assessment. The comprehensive assessment must accurately reflect the patient's status, and must include, at a minimum, the following information:

(1) The patient’s current health, psychosocial, functional, and cognitive status;

(2) The patient’s strengths, goals, and care preferences, including information that may be used to demonstrate the patient's progress toward achievement of the goals identified by the patient and the measurable outcomes identified by the HHA;

(3) The patient's continuing need for home care;

(4) The patient's medical, nursing, rehabilitative, social, and discharge planning

needs;

(5) A review of all medications the patient is currently using in order to identify any potential adverse effects and drug reactions, including ineffective drug therapy, significant side effects, significant drug interactions, duplicate drug therapy, and noncompliance with drug therapy.

(6) The patient's primary caregiver(s), if any, and other available supports;

(7) The patient's representative (if any);

(8) Incorporation of the current version of the Outcome and Assessment Information Set (OASIS) items, using the language and groupings of the OASIS items, as specified by the Secretary. The OASIS data items determined by the Secretary must include: clinical record items, demographics and patient history, living arrangements, supportive assistance, sensory status, integumentary status, respiratory status, elimination status, neuro/emotional/behavioral status, activities of daily living, medications, equipment management, emergent care, and data items collected at inpatient facility admission or discharge only.

(d) Standard: Update of the comprehensive assessment. The comprehensive assessment must be updated and revised (including the administration of the OASIS) as frequently as the patient's condition warrants due to a major decline or improvement in the patient's health status, but not less frequently than—

(1) The last five days of every 60 days beginning with the start-of-care date, unless there is a—

(i) Beneficiary elected transfer;

(ii) Significant change in condition; or

(iii) Discharge and return to the same HHA during the 60-day episode.

(2) Within 48 hours of the patient's return to the home from a hospital admission of 24 hours or more for any reason other than diagnostic tests, or on physician-ordered resumption date;

(3) At discharge.

§484.60 Condition of participation: Care planning, coordination of services, and quality of care.

Patients are accepted for treatment on the reasonable expectation that an HHA can meet the patient's medical, nursing, rehabilitative, and social needs in his or her place of residence. Each patient must receive an individualized written plan of care, including any revisions or additions. The individualized plan of care must specify the care and services necessary to meet the patient-specific needs as identified in the comprehensive assessment, including identification of the responsible discipline(s), and the measurable outcomes that the HHA anticipates will occur as a result of implementing and coordinating the plan of care. The individualized plan of care must also specify the patient and caregiver education and training that the HHA will provide, specific to the patient's care needs. Services must be furnished in accordance with accepted standards of practice.

(a) Standard: Plan of care. (1) Each patient must receive the home health services that are written in an individualized plan of care that identifies patient-specific measurable outcomes and goals, and which is established, periodically reviewed, and signed by a doctor of medicine, osteopathy, or podiatry acting within the scope of his or her state

license, certification, or registration. If a physician refers a patient under a plan of care that cannot be completed until after an evaluation visit, the physician is consulted to approve additions or modifications to the original plan.

(2) The individualized plan of care must include the following:

(i) All pertinent diagnoses;

(ii) The patient's mental, psychosocial, and cognitive status;

(iii) The types of services, supplies, and equipment required;

(iv) The frequency and duration of visits to be made;

(v) Prognosis;

(vi) Rehabilitation potential;

(vii) Functional limitations;

(viii) Activities permitted;

(ix) Nutritional requirements;

(x) All medications and treatments;

(xi) Safety measures to protect against injury;

(xii) Patient and caregiver education and training to facilitate timely discharge;

(xiii) Patient-specific interventions and education; measurable outcomes and goals identified by the HHA and the patient;

(xiv) Information related to any advanced directives; and

(xv) Any additional items the HHA or physician may choose to include.

(3) If HHA services are initiated following the patient's discharge from a hospital, the individualized plan of care must include a description of the patient's risk for

emergency department visits and hospital re-admission (low, medium, high) and all necessary interventions to address the underlying risk factors.

(4) All patient care orders, including verbal orders, must be recorded in the plan of care.

(b) Standard: Conformance with physician orders. (1) Drugs, services, and treatments are administered only as ordered by the physician who is responsible for the home health plan of care.

(2) Influenza and pneumococcal vaccines may be administered per agency policy developed in consultation with a physician, and after an assessment of the patient to determine for contraindications.

(3) Verbal orders must be accepted only by personnel authorized to do so by applicable state laws and regulations and by the HHA's internal policies.

(4) When services are provided on the basis of a physician's verbal orders, a registered nurse, or other qualified practitioner responsible for furnishing or supervising the ordered services, in accordance with state law and the HHA's policies, must document the orders in the patient's clinical record, and sign, date, and time the orders. Verbal orders must be authenticated and dated by the physician in accordance with applicable state laws and regulations, as well as the HHA's internal policies.

(c) Standard: Review and revision of the plan of care. (1) The individualized plan of care must be reviewed and revised by the physician who is responsible for the home health plan of care and the HHA as frequently as the patient's condition or needs require, but no less frequently than once every 60 days, beginning with the start of care date. The HHA

must promptly alert the physician who is responsible for the HHA plan of care to any changes in the patient's condition or needs that suggest that outcomes are not being achieved and/or that the plan of care should be altered.

(2) A revised plan of care must reflect current information from the patient's updated comprehensive assessment, and contain information concerning the patient's progress toward the measurable outcomes and goals identified by the HHA and patient in the plan of care.

(3) Revisions to the plan of care must be communicated as follows:

(i) Any revision to the plan of care due to a change in patient health status must be communicated to the patient, representative (if any), caregiver, and the physician who is responsible for the HHA plan of care.

(ii) Any revisions related to plans for the patient's discharge must be communicated to the patient, representative, caregiver, the physician who is responsible for the HHA plan of care, and the patient's primary care practitioner or other health care professional who will be responsible for providing care and services to the patient after discharge from the HHA (if any).

(d) Standard: Coordination of care. (l) The HHA must integrate services, whether services are provided directly or under arrangement, to assure the identification of patient needs and factors that could affect patient safety and treatment effectiveness, the coordination of care provided by all disciplines, and communication with the physician.

(2) The HHA coordinates care delivery to meet the patient's needs, and involves the patient, representative (if any), and caregiver(s), as appropriate, in the coordination of care

activities.

(3) The HHA must ensure that each patient, and his or her caregiver(s) where applicable, receive ongoing education and training provided by the HHA, as appropriate, regarding the care and services identified in the plan of care. The HHA must provide training, as necessary, to ensure a timely discharge.

(e) Standard: Discharge or transfer summary. The discharge or transfer summary must include—

(1) A summary of the patient's stay, including the reason for referral to the HHA, the patient's clinical, mental, psychosocial, cognitive, and functional condition at the time of the start of services by the HHA, all services provided by the HHA, the start and end date of care by the HHA, the patient's clinical, mental, psychosocial, cognitive, and functional condition at the time of discharge from the HHA, an updated reconciled list of medications at the time of discharge or transfer, and any recommendations for ongoing care (for example, outpatient physical therapy);

(2) The patient's current plan of care, including the latest physician orders; and

(3) Any other documentation that will assist in post-discharge or transfer continuity of care, or that is requested by the health care practitioner who will be responsible for providing care and services to the patient after discharge from the HHA or receiving facility.

§484.65 Condition of participation: Quality assessment and performance improvement (QAPI).

The HHA must develop, implement, evaluate, and maintain an effective, ongoing,

HHA-wide, data-driven QAPI program. The HHA's governing body must ensure that the program reflects the complexity of its organization and services; involves all HHA services (including those services provided under contract or arrangement); focuses on indicators related to improved outcomes, including hospital admissions and re-admissions; and takes actions that address the HHA's performance across the spectrum of care, including the prevention and reduction of medical errors. The HHA must maintain documentary evidence of its QAPI program and be able to demonstrate its operation to CMS.

(a) Standard: Program scope. (1) The program must at least be capable of showing measurable improvement in indicators for which there is evidence that improvement in those indicators will improve health outcomes, patient safety, and quality of care.

(2) The HHA must measure, analyze, and track quality indicators, including adverse patient events, and other aspects of performance that enable the HHA to assess processes of care, HHA services, and operations.

(b) Standard: Program data. (1) The program must utilize quality indicator data, including measures derived from OASIS, where applicable, and other relevant data, in the design of its program.

(2) The HHA must use the data collected to--

(i) Monitor the effectiveness and safety of services and quality of care; and

(ii) Identify opportunities for improvement.

(3) The frequency and detail of the data collection must be approved by the HHA's governing body.

(c) Standard: Program activities. (1) The HHA's performance improvement

activities must—

(i) Focus on high risk, high volume, or problem-prone areas;

(ii) Consider incidence, prevalence, and severity of problems in those areas; and

(iii) Lead to an immediate correction of any identified problem that directly or potentially threaten the health and safety of patients.

(2) Performance improvement activities must track adverse patient events, analyze their causes, and implement preventive actions.

(3) The HHA must take actions aimed at performance improvement, and, after implementing those actions, the HHA must measure its success and track performance to ensure that improvements are sustained.

(d) Standard: Performance improvement projects. (1) The number and scope of distinct improvement projects conducted annually must reflect the scope, complexity, and past performance of the HHA's services and operations.

(2) The HHA must document the quality improvement projects undertaken, the reasons for conducting these projects, and the measurable progress achieved on these projects.

(e) Standard: Executive responsibilities. The HHA's governing body is responsible for ensuring the following:

(1) That an ongoing program for quality improvement and patient safety is defined, implemented, and maintained;

(2) That the HHA-wide quality assessment and performance improvement efforts address priorities for improved quality of care and patient safety, and that all improvement

actions are evaluated for effectiveness;

(3) That clear expectations for patient safety are established, implemented, and maintained; and

(4) That any findings of fraud or waste are appropriately addressed.

§484.70 Condition of participation: Infection prevention and control.

The HHA must maintain and document an infection control program which has as its goal the prevention and control of infections and communicable diseases.

(a) Standard: Prevention. The HHA must follow accepted standards of practice, including the use of standard precautions, to prevent the transmission of infections and communicable diseases.

(b) Standard: Control. The HHA must maintain a coordinated agency-wide program for the surveillance, identification, prevention, control, and investigation of infectious and communicable diseases that is an integral part of the HHA's quality assessment and performance improvement (QAPI) program. The infection control program must include:

(1) A method for identifying infectious and communicable disease problems; and

(2) A plan for the appropriate actions that are expected to result in improvement and disease prevention.

(c) Standard: Education. The HHA must provide infection control education to staff, patients, and caregiver(s).

§484.75 Condition of participation: Skilled professional services.

Skilled professional services include skilled nursing services, physical therapy,

speech-language pathology services, and occupational therapy, as specified in §409.44 of this chapter, and physician and medical social work services as specified in §409.45 of this chapter. Skilled professionals who provide services to HHA patients directly or under arrangement must participate in the coordination of care.

(a) Standard: Provision of services by skilled professionals. Skilled professional services are authorized, delivered, and supervised only by health care professionals who meet the appropriate qualifications specified under §484.115 and who practice according to the HHA's policies and procedures.

(b) Standard: Responsibilities of skilled professionals. Skilled professionals must assume responsibility for, but not be restricted to, the following:

(1) Ongoing interdisciplinary assessment of the patient;

(2) Development and evaluation of the plan of care in partnership with the patient, representative (if any), and caregiver(s);

(3) Providing services that are ordered by the physician as indicated in the plan of care;

(4) Patient, caregiver, and family counseling;

(5) Patient and caregiver education;

(6) Preparing clinical notes;

(7) Communication with the physician who is responsible for the home health plan of care and other health care practitioners (as appropriate) related to the current plan of care;

(8) Participation in the HHA’s QAPI program; and

(9) Participation in HHA-sponsored in-service training.

(c) Supervision of skilled professional assistants. (1) Nursing services are provided under the supervision of a registered nurse that meets the requirements of §484.115(j).

(2) Rehabilitative therapy services are provided under the supervision of an occupational therapist or physical therapist that meets the requirements of §484.115(e) or (g), respectively.

(3) Medical social services are provided under the supervision of a social worker that meets the requirements of §484.115(l).

§484.80 Condition of participation: Home health aide services.

All home health aide services must be provided by individuals who meet the personnel requirements specified in paragraph (a) of this section.

(a) Standard: Home health aide qualifications. (1) A qualified home health aide is a person who has successfully completed:

(i) A training and competency evaluation program as specified in paragraphs (b) and (c), respectively, of this section; or

(ii) A competency evaluation program that meets the requirements of paragraph (c) of this section; or

(iii) A nurse aide training and competency evaluation program approved by the state as meeting the requirements of §§483.151 through 483.154 of this chapter, and is currently listed in good standing on the state nurse aide registry; or

(iv) The requirements of a state licensure program that meets the provisions of paragraphs (b) and (c) of this section.

(2) A home health aide or nurse aide is not considered to have completed a program, as specified in paragraph (a)(1) of this section, if, since the individual's most recent completion of the program(s), there has been a continuous period of 24 consecutive months during which none of the services furnished by the individual as described in §409.40 of this chapter were for compensation. If there has been a 24-month lapse in furnishing services for compensation, the individual must complete another program, as specified in paragraph (a)(1) of this section, before providing services.

(b) Standard: Content and duration of home health aide classroom and supervised practical training. (1) Home health aide training must include classroom and supervised practical training in a practicum laboratory or other setting in which the trainee demonstrates knowledge while providing services to an individual under the direct supervision of a registered nurse, or a licensed practical nurse who is under the supervision of a registered nurse. Classroom and supervised practical training must total at least 75 hours.

(2) A minimum of 16 hours of classroom training must precede a minimum of l6 hours of supervised practical training as part of the 75 hours.

(3) A home health aide training program must address each of the following subject areas:

(i) Communication skills, including the ability to read, write, and verbally report clinical information to patients, representatives, and caregivers, as well as to other HHA staff.

(ii) Observation, reporting, and documentation of patient status and the care or

service furnished.

(iii) Reading and recording temperature, pulse, and respiration.

(iv) Basic infection prevention and control procedures.

(v) Basic elements of body functioning and changes in body function that must be reported to an aide's supervisor.

(vi) Maintenance of a clean, safe, and healthy environment.

(vii) Recognizing emergencies and the knowledge of instituting emergency procedures and their application.

(viii) The physical, emotional, and developmental needs of and ways to work with the populations served by the HHA, including the need for respect for the patient, his or her privacy, and his or her property.

(ix) Appropriate and safe techniques in performing personal hygiene and grooming tasks that include --

(A) Bed bath;

(B) Sponge, tub, and shower bath;

(C) Hair shampooing in sink, tub, and bed;

(D) Nail and skin care;

(E) Oral hygiene;

(F) Toileting and elimination;

(x) Safe transfer techniques and ambulation;

(xi) Normal range of motion and positioning;

(xii) Adequate nutrition and fluid intake;

(xiii) Recognizing and reporting changes in skin condition, including pressure ulcers; and

(xiv) Any other task that the HHA may choose to have an aide perform as permitted under state law.

(xv) The HHA is responsible for training home health aides, as needed, for skills not covered in the basic checklist, as described in paragraph (b)(3)(ix) of this section.

(4) The HHA must maintain documentation that demonstrates that the requirements of this standard have been met.

(c) Standard: Competency evaluation. An individual may furnish home health services on behalf of an HHA only after that individual has successfully completed a competency evaluation program as described in this section.

(1) The competency evaluation must address each of the subjects listed in paragraph (b)(3) of this section. Subject areas specified under paragraphs (b)(3)(i), (iii), (ix), (x), and (xi) of this section must be evaluated by observing an aide's performance of the task with a patient. The remaining subject areas may be evaluated through written examination, oral examination, or after observation of a home health aide with a patient.

(2) A home health aide competency evaluation program may be offered by any organization, except as specified in paragraph (f) of this section.

(3) The competency evaluation must be performed by a registered nurse in consultation with other skilled professionals, as appropriate.

(4) A home health aide is not considered competent in any task for which he or she is evaluated as unsatisfactory. An aide must not perform that task without direct

supervision by a registered nurse until after he or she has received training in the task for which he or she was evaluated as "unsatisfactory," and has successfully completed a subsequent evaluation. A home health aide is not considered to have successfully passed a competency evaluation if the aide has an "unsatisfactory" rating in more than one of the required areas.

(5) The HHA must maintain documentation which demonstrates that the requirements of this standard have been met.

(d) Standard: In-service training. A home health aide must receive at least l2 hours of in-service training during each 12-month period. In-service training may occur while an aide is furnishing care to a patient.

(1) In-service training may be offered by any organization and must be supervised by a registered nurse.

(2) The HHA must maintain documentation that demonstrates the requirements of this standard have been met.

(e) Standard: Qualifications for instructors conducting classroom and supervised practical training. Classroom and supervised practical training must be performed by a registered nurse who possesses a minimum of 2 years nursing experience, at least 1 year of which must be in home health care, or by other individuals under the general supervision of the registered nurse.

(f) Standard: Eligible training and competency evaluation organizations. A home health aide training program and competency evaluation program may be offered by any organization except by an HHA that, within the previous 2 years:

(1) Was out of compliance with the requirements of paragraphs (b), (c), (d), or (e) of this section; or

(2) Permitted an individual who does not meet the definition of a “qualified home health aide” as specified in paragraph (a) of this section to furnish home health aide services (with the exception of licensed health professionals and volunteers); or

(3) Was subjected to an extended (or partially extended) survey as a result of having been found to have furnished substandard care (or for other reasons as determined by CMS or the State); or

(4) Was assessed a civil monetary penalty of $5,000 or more as an intermediate sanction; or

(5) Was found to have compliance deficiencies that endangered the health and safety of the HHA's patients, and had temporary management appointed to oversee the management of the HHA; or

(6) Had all or part of its Medicare payments suspended; or

(7) Was found under any federal or state law to have:

(i) Had its participation in the Medicare program terminated; or

(ii) Been assessed a penalty of $5,000 or more for deficiencies in federal or state standards for HHAs; or

(iii) Been subjected to a suspension of Medicare payments to which it otherwise would have been entitled; or

(iv) Operated under temporary management that was appointed to oversee the operation of the HHA and to ensure the health and safety of the HHA's patients; or

(v) Been closed, or had its patients transferred by the state; or

(vi) Been excluded from participating in federal health care programs or debarred from participating in any government program.

(g) Standard: Home health aide assignments and duties. (l) Home health aides are assigned to a specific patient by a registered nurse or other appropriate skilled professional. Written patient care instructions for a home health aide must be prepared by a registered nurse or other appropriate skilled professional (that is, physical therapist, speech-language pathologist, or occupational therapist) who is responsible for the supervision of a home health aide as specified under paragraph (h) of this section.

(2) A home health aide provides services that are:

(i) Ordered by the physician;

(ii) Included in the plan of care;

(iii) Permitted to be performed under state law; and

(iv) Consistent with the home health aide training.

(3) The duties of a home health aide include:

(i) The provision of hands-on personal care;

(ii) The performance of simple procedures as an extension of therapy or nursing services;

(iii) Assistance in ambulation or exercises; and

(iv) Assistance in administering medications ordinarily self-administered.

(4) Home health aides must be members of the interdisciplinary team, must report changes in the patient's condition to a registered nurse or other appropriate skilled

professional, and must complete appropriate records in compliance with the HHA's policies and procedures.

(h) Standard: Supervision of home health aides. (1) (i) If home health aide services are provided to a patient who is receiving skilled nursing, physical or occupational therapy, or speech-language pathology services, a registered nurse or other appropriate skilled professional described in paragraph (g) of this section must make an onsite visit to the patient's home no less frequently than every 14 days. The home health aide does not have to be present during this visit.

(ii) If a potential deficiency in aide services is noted by the supervising registered nurse or other appropriate skilled professional, then the supervising individual must make an on-site visit to the location where the patient is receiving care in order to observe and assess the aide while he or she is performing care.

(iii) A registered nurse or other appropriate skilled professional must make an annual on-site visit to the location where a patient is receiving care in order to observe and assess each aide while he or she is performing care.

(2) If home health aide services are provided to a patient who is not receiving skilled nursing care, physical or occupational therapy, or speech-language pathology services, the registered nurse must make an on-site visit to the location where the patient is receiving care no less frequently than every 60 days in order to observe and assess each aide while he or she is performing care.

(3) If a deficiency in aide services is verified by the registered nurse or other appropriate skilled professional during an on-site visit, then the agency must conduct, and

the home health aide must complete a competency evaluation in accordance with paragraph (c) of this section.

(4) Home health aide supervision must ensure that aides furnish care in a safe and effective manner, including, but not limited to, the following elements:

(i) Following the patient's plan of care for completion of tasks assigned to a home health aide by the registered nurse or other appropriate skilled professional;

(ii) Maintaining an open communication process with the patient, representative (if any), caregivers, and family;

(iii) Demonstrating competency with assigned tasks;

(iv) Complying with infection prevention and control policies and procedures;

(v) Reporting changes in the patient's condition; and

(vi) Honoring patient rights.

(5) If the home health agency chooses to provide home health aide services under arrangements, as defined in section 1861(w)(1) of the Act, the HHA's responsibilities also include, but are not limited to:

(i) Ensuring the overall quality of care provided by an aide;

(ii) Supervising aide services as described in paragraphs (h)(l) and (2) of this section; and

(iii) Ensuring that home health aides who provide services under arrangement have met the training or competency evaluation requirements, or both, of this part.

(i) Standard: Individuals furnishing Medicaid personal care aide-only services under a Medicaid personal care benefit. An individual may furnish personal care services,

as defined in §440.167 of this chapter, on behalf of an HHA. Before the individual may furnish personal care services, the individual must meet all qualification standards established by the state. The individual only needs to demonstrate competency in the services the individual is required to furnish.

Subpart C--Organizational Environment

§484.100 Condition of participation: Compliance with Federal, State, and local laws and regulations related to the health and safety of patients.

The HHA and its staff must operate and furnish services in compliance with all applicable federal, state, and local laws and regulations related to the health and safety of patients. If state or local law provides licensing of HHAs, the HHA must be licensed.

(a) Standard: Disclosure of ownership and management information. The HHA must comply with the requirements of part 420, subpart C, of this chapter. The HHA also must disclose the following information to the state survey agency at the time of the HHA's initial request for certification, for each survey, and at the time of any change in ownership or management:

(l) The names and addresses of all persons with an ownership or controlling interest in the HHA as defined in §§ 420.20l, 420.202, and 420.206 of this chapter.

(2) The name and address of each person who is an officer, a director, an agent, or a managing employee of the HHA as defined in §§ 420.20l, 420.202, and 420.206 of this chapter.

(3) The name and business address of the corporation, association, or other company that is responsible for the management of the HHA, and the names and addresses

of the chief executive officer and the chairperson of the board of directors of that corporation, association, or other company responsible for the management of the HHA.

(b) Standard: Licensing. The HHA, its branches, and all persons furnishing services to patients must be licensed, certified, or registered, as applicable, in accordance with the state licensing authority as meeting those requirements.

(c) Standard: Laboratory services. (l) If the HHA engages in laboratory testing outside of the context of assisting an individual in self-administering a test with an appliance that has been cleared for that purpose by the Food and Drug Administration, the testing must be in compliance with all applicable requirements of part 493 of this chapter. The HHA may not substitute its equipment for a patient's equipment when assisting with self-administered tests.

(2) If the HHA refers specimens for laboratory testing, the referral laboratory must be certified in the appropriate specialties and subspecialties of services in accordance with the applicable requirements of part 493 of this chapter.

§484.105 Condition of participation: Organization and administration of services.

The HHA must organize, manage, and administer its resources to attain and maintain the highest practicable functional capacity, including overcoming those deficits that led to the patient's need for home health services, for each patient's medical, nursing, and rehabilitative needs as indicated by the plan of care. The HHA must assure that administrative and supervisory functions are not delegated to another agency or organization, and all services not furnished directly are monitored and controlled. The HHA must set forth, in writing, its organizational structure, including lines of authority,

and services furnished.

(a) Standard: Governing body. A governing body (or designated persons so functioning) must assume full legal authority and responsibility for the agency's overall management and operation, the provision of all home health services, fiscal operations, review of the agency's budget and its operational plans, and its quality assessment and performance improvement program.

(b) Standard: Administrator. (1) The administrator must:

(i) Be appointed by the governing body;

(ii) Be responsible for all day-to-day operations of the HHA;

(iii) Ensure that a skilled professional as described in §484.75 is available during all operating hours.

(2) When the administrator is not available, a pre-designated person, who is authorized in writing by the administrator and the governing body, assumes the same responsibilities and obligations as the administrator. The pre-designated person may be the skilled professional as described in paragraph (b)(1)(iii) of this section.

(3) The administrator or pre-designated individual is available during all operating hours.

(c) Clinical manager. A qualified licensed physician or registered nurse must provide oversight of all patient care services and personnel. Oversight must include the following--

(1) Making patient and personnel assignments;

(2) Coordinating patient care;

(3) Coordinating referrals;

(4) Assuring that patient needs are continually assessed;

(5) Assuring the development, implementation, and updates of the individualized plan of care; and

(6) Assuring the development of personnel qualifications and policies.

(d) Standard: Parent-branch relationship. (1) The parent HHA is responsible for reporting all branch locations of the HHA to the state survey agency at the time of the HHA's request for initial certification, at each survey, and at the time the parent proposes to add or delete a branch.

(2) The parent HHA provides direct support and administrative control of its branches.

(e) Standard: Services under arrangement. (1) The HHA must ensure that all services furnished under arrangement provided by other entities or individuals meet the requirements of this part and the requirements of section 1861(w) of the Act (42 U.S.C. 1395x (w)).

(2) An HHA must have a written agreement with another agency, with an organization, or with an individual when that entity or individual furnishes services under arrangement to the HHA's patients. The HHA must maintain overall responsibility for the services provided under arrangement, as well as the manner in which they are furnished. The agency, organization, or individual providing services under arrangement may not have been:

(i) Denied Medicare or Medicaid enrollment;

(ii) Been excluded or terminated from any Federal health care program or Medicaid;

(iii) Had its Medicare or Medicaid billing privileges revoked; or

(iv) Been debarred from participating in any government program.

(3) The primary HHA is responsible for patient care, and must conduct and provide, either directly or under arrangements, all services rendered to patients.

(f) Standard: Services furnished. (1) Skilled nursing services and at least one other therapeutic service (physical therapy, speech-language pathology, or occupational therapy; medical social services; or home health aide services) are made available on a visiting basis, in a place of residence used as a patient's home. An HHA must provide at least one of the services described in this subsection directly, but may provide the second service and additional services under arrangement with another agency or organization.

(2) All HHA services must be provided in accordance with current clinical practice guidelines and accepted professional standards of practice.

(g) Standard: Outpatient physical therapy or speech-language pathology services. An HHA that furnishes outpatient physical therapy or speech-language pathology services must meet all of the applicable conditions of this part and the additional health and safety requirements set forth in §§ 485.711, 485.713, 485.715, 485.719, 485.723, and 485.727 of this chapter to implement section 1861(p) of the Act.

(h) Standard: Institutional planning. The HHA, under the direction of the governing body, prepares an overall plan and a budget that includes an annual operating budget and capital expenditure plan.

(1) Annual operating budget. There is an annual operating budget that includes all anticipated income and expenses related to items that would, under generally accepted accounting principles, be considered income and expense items. However, it is not required that there be prepared, in connection with any budget, an item by item identification of the components of each type of anticipated income or expense.

(2) Capital expenditure plan. (i) There is a capital expenditure plan for at least a 3-year period, including the operating budget year. The plan includes and identifies in detail the anticipated sources of financing for, and the objectives of, each anticipated expenditure of more than $600,000 for items that would under generally accepted accounting principles, be considered capital items. In determining if a single capital expenditure exceeds $600,000, the cost of studies, surveys, designs, plans, working drawings, specifications, and other activities essential to the acquisition, improvement, modernization, expansion, or replacement of land, plant, building, and equipment are included. Expenditures directly or indirectly related to capital expenditures, such as grading, paving, broker commissions, taxes assessed during the construction period, and costs involved in demolishing or razing structures on land are also included. Transactions that are separated in time, but are components of an overall plan or patient care objective, are viewed in their entirety without regard to their timing. Other costs related to capital expenditures include title fees, permit and license fees, broker commissions, architect, legal, accounting, and appraisal fees; interest, finance, or carrying charges on bonds, notes and other costs incurred for borrowing funds.

(ii) If the anticipated source of financing is, in any part, the anticipated payment from title V (Maternal and Child Health Services Block Grant) or title XVIII (Medicare) or title XIX (Medicaid) of the Social Security Act, the plan specifies the following:

(A) Whether the proposed capital expenditure is required to conform, or is likely to be required to conform, to current standards, criteria, or plans developed in accordance with the Public Health Service Act or the Mental Retardation Facilities and Community Mental Health Centers Construction Act of 1963.

(B) Whether a capital expenditure proposal has been submitted to the designated planning agency for approval in accordance with section 1122 of the Act (42 U.S.C. 1320a-1) and implementing regulations.

(C) Whether the designated planning agency has approved or disapproved the proposed capital expenditure if it was presented to that agency.

(3) Preparation of plan and budget. The overall plan and budget is prepared under the direction of the governing body of the HHA by a committee consisting of representatives of the governing body, the administrative staff, and the medical staff (if any) of the HHA.

(4) Annual review of plan and budget. The overall plan and budget is reviewed and updated at least annually by the committee referred to in paragraph (i)(3) of this section under the direction of the governing body of the HHA.

§484.110 Condition of participation: Clinical records.

The HHA must maintain a clinical record containing past and current information for every patient accepted by the HHA and receiving home health services. Information

contained in the clinical record must be accurate, adhere to current clinical record documentation standards of practice, and be available to the physician who is responsible for the home health plan of care, and appropriate HHA staff. This information may be maintained electronically.

(a) Standard: Contents of clinical record. The record must include:

(1) The patient's current comprehensive assessment, including all of the assessments from the most recent home health admission, clinical notes, plans of care, and physician orders;

(2) All interventions, including medication administration, treatments, and services, and responses to those interventions;

(3) Goals in the patient's plans of care and the patient's progress toward achieving them;

(4) Contact information for the patient and the patient's representative (if any);

(5) Contact information for the primary care practitioner or other health care professional who will be responsible for providing care and services to the patient after discharge from the HHA; and

(6) A completed discharge or transfer summary, as required by §484.60(e), that is sent to the primary care practitioner or other health care professional who will be responsible for providing care and services to the patient after discharge from the HHA (if any) within 7 calendar days of the patient's discharge; or, if the patient's care will be immediately continued in a health care facility, a discharge or transfer summary is sent to the facility within 2 calendar days of the patient's discharge or transfer.

(b) Standard: Authentication. All entries must be legible, clear, complete, and appropriately authenticated, dated, and timed. Authentication must include a signature and a title (occupation), or a secured computer entry by a unique identifier, of a primary author who has reviewed and approved the entry.

(c) Standard: Retention of records. (1) Clinical records must be retained for 5 years after the discharge of the patient, unless state law stipulates a longer period of time.

(2) The HHA's policies must provide for retention of clinical records even if it discontinues operation. When an HHA discontinues operation, it must inform the state agency where clinical records will be maintained.

(d) Standard: Protection of records. The clinical record, its contents, and the information contained therein must be safeguarded against loss or unauthorized use. The HHA must be in compliance with the rules regarding personal health information set out at 45 CFR parts 160 and 164.

(e) Standard: Retrieval of clinical records. A patient's clinical record (whether hard copy or electronic form) must be made available to a patient and appropriately authorized individuals or entities upon request.

§484.115 Condition of participation: Personnel qualifications.

HHA staff are required to meet the following standards:

(a) Standard: Administrator, home health agency. A person who:

(1) Is a licensed physician, a registered nurse, or holds an undergraduate degree; and

(2) Has experience in health service administration, with at least one year of

supervisory or administrative experience in home health care or a related health care program.

(b) Standard: Audiologist. A person who:

(1) Meets the education and experience requirements for a Certificate of Clinical Competence in audiology granted by the American Speech-Language-Hearing Association; or

(2) Meets the educational requirements for certification and is in the process of accumulating the supervised experience required for certification.

(c) Standard: Home health aide. A person who meets the qualifications for home health aides specified in section 1891(a)(3) of the Act and implemented at §484.80.

(d) Standard: Licensed practical nurse. A person who has completed a practical nursing program, is licensed in the state where practicing, and who furnishes services under the supervision of a qualified registered nurse.

(e) Standard: Occupational therapist. A person who—

(1)(i) Is licensed or otherwise regulated, if applicable, as an occupational therapist by the state in which practicing, unless licensure does not apply;

(ii) Graduated after successful completion of an occupational therapist education program accredited by the Accreditation Council for Occupational Therapy Education (ACOTE) of the American Occupational Therapy Association, Inc. (AOTA), or successor organizations of ACOTE; and

(iii) Is eligible to take, or has successfully completed the entry-level certification examination for occupational therapists developed and administered by the National Board

for Certification in Occupational Therapy, Inc. (NBCOT).

(2) On or before December 31, 2009—

(i) Is licensed or otherwise regulated, if applicable, as an occupational therapist by the state in which practicing; or

(ii) When licensure or other regulation does not apply—

(A) Graduated after successful completion of an occupational therapist education program accredited by the accreditation Council for Occupational Therapy Education (ACOTE) of the American Occupational Therapy Association, Inc. (AOTA) or successor organizations of ACOTE; and

(B) Is eligible to take, or has successfully completed the entry-level certification examination for occupational therapists developed and administered by the National Board for Certification in Occupational Therapy, Inc., (NBCOT).

(3) On or before January 1, 2008—

(i) Graduated after successful completion of an occupational therapy program accredited jointly by the Committee on Allied Health Education and Accreditation of the American Medical Association and the American Occupational Therapy Association; or

(ii) Is eligible for the National Registration Examination of the American Occupational Therapy Association or the National Board for Certification in Occupational Therapy.

(4) On or before December 31, 1977—

(i) Had 2 years of appropriate experience as an occupational therapist; and

(ii) Had achieved a satisfactory grade on an occupational therapist proficiency

examination conducted, approved, or sponsored by the U.S. Public Health Service.

(5) If educated outside the United States, must meet both of the following:

(i) Graduated after successful completion of an occupational therapist education program accredited as substantially equivalent to occupational therapist assistant entry level education in the United States by one of the following:

(A) The Accreditation Council for Occupational Therapy Education (ACOTE).

(B) Successor organizations of ACOTE.

(C) The World Federation of Occupational Therapists.

(D) A credentialing body approved by the American Occupational Therapy Association.

(E) Successfully completed the entry level certification examination for occupational therapists developed and administered by the National Board for Certification in Occupational Therapy, Inc. (NBCOT).

(ii) On or before December 31, 2009, is licensed or otherwise regulated, if applicable, as an occupational therapist by the state in which practicing.

(f) Standard: Occupational therapy assistant. A person who—

(1) Meets all of the following:

(i) Is licensed or otherwise regulated, if applicable, as an occupational therapy assistant by the state in which practicing, unless licensure does apply.

(ii) Graduated after successful completion of an occupational therapy assistant education program accredited by the Accreditation Council for Occupational Therapy Education, (ACOTE) of the American Occupational Therapy Association, Inc. (AOTA) or

its successor organizations.

(iii) Is eligible to take or successfully completed the entry-level certification examination for occupational therapy assistants developed and administered by the National Board for Certification in Occupational Therapy, Inc. (NBCOT).

(2) On or before December 31, 2009—

(i) Is licensed or otherwise regulated as an occupational therapy assistant, if applicable, by the state in which practicing; or any qualifications defined by the state in which practicing, unless licensure does not apply; or

(ii) Must meet both of the following:

(A) Completed certification requirements to practice as an occupational therapy assistant established by a credentialing organization approved by the American Occupational Therapy Association.

(B) After January 1, 2010, meets the requirements in paragraph (b)(6)(i) of this section.

(3) After December 31, 1977 and on or before December 31, 2007—

(i) Completed certification requirements to practice as an occupational therapy assistant established by a credentialing organization approved by the American Occupational Therapy Association; or

(ii) Completed the requirements to practice as an occupational therapy assistant applicable in the state in which practicing.

(4) On or before December 31, 1977—

(i) Had 2 years of appropriate experience as an occupational therapy assistant; and

(ii) Had achieved a satisfactory grade on an occupational therapy assistant proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service.

(5) If educated outside the United States, on or after January 1, 2008—

(i) Graduated after successful completion of an occupational therapy assistant education program that is accredited as substantially equivalent to occupational therapist assistant entry level education in the United States by—

(A) The Accreditation Council for Occupational Therapy Education (ACOTE).

(B) Its successor organizations.

(C) The World Federation of Occupational Therapists.

(D) By a credentialing body approved by the American Occupational Therapy Association; and

(E) Successfully completed the entry level certification examination for occupational therapy assistants developed and administered by the National Board for Certification in Occupational Therapy, Inc. (NBCOT).

(ii) [Reserved]

(g) Standard: Physical therapist. A person who is licensed, if applicable, by the state in which practicing, unless licensure does not apply and meets one of the following requirements:

(1) Graduated after successful completion of a physical therapist education program approved by one of the following:

(i) The Commission on Accreditation in Physical Therapy Education (CAPTE).

(ii) Successor organizations of CAPTE.

(iii) An education program outside the United States determined to be substantially equivalent to physical therapist entry level education in the United States by a credentials evaluation organization approved by the American Physical Therapy Association or an organization identified in 8 CFR 212.15(e) as it relates to physical therapists.

(iv) Passed an examination for physical therapists approved by the state in which physical therapy services are provided.

(2) On or before December 31, 2009—

(i) Graduated after successful completion of a physical therapy curriculum approved by the Commission on Accreditation in Physical Therapy Education (CAPTE); or

(ii) Meets both of the following:

(A) Graduated after successful completion of an education program determined to be substantially equivalent to physical therapist entry level education in the United States by a credentials evaluation organization approved by the American Physical Therapy Association or identified in 8 CFR 212.15(e) as it relates to physical therapists.

(B) Passed an examination for physical therapists approved by the state in which physical therapy services are provided.

(3) Before January 1, 2008—

(i) Graduated from a physical therapy curriculum approved by one of the following:

(A) The American Physical Therapy Association.

(B) The Committee on Allied Health Education and Accreditation of the American Medical Association.

(C) The Council on Medical Education of the American Medical Association and the American Physical Therapy Association.

(ii) [Reserved]

(4) On or before December 31, 1977 was licensed or qualified as a physical therapist and meets both of the following:

(i) Has 2 years of appropriate experience as a physical therapist.

(ii) Has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service.

(5) Before January 1, 1966—

(i) Was admitted to membership by the American Physical Therapy Association;

(ii) Was admitted to registration by the American Registry of Physical Therapists; and

(iii) Graduated from a physical therapy curriculum in a 4-year college or university approved by a state department of education.

(6) Before January 1, 1966 was licensed or registered, and before January 1, 1970, had 15 years of fulltime experience in the treatment of illness or injury through the practice of physical therapy in which services were rendered under the order and direction of attending and referring doctors of medicine or osteopathy.

(7) If trained outside the United States before January 1, 2008, meets the following requirements:

(i) Was graduated since 1928 from a physical therapy curriculum approved in the country in which the curriculum was located and in which there is a member organization

of the World Confederation for Physical Therapy.

(ii) Meets the requirements for membership in a member organization of the World Confederation for Physical Therapy.

(h) Standard: Physical therapist assistant. A person who is licensed, registered or certified as a physical therapist assistant, if applicable, by the state in which practicing, unless licensure does not apply and meets one of the following requirements:

(1) Graduated from a physical therapist assistant curriculum approved by the Commission on Accreditation in Physical Therapy Education of the American Physical Therapy Association; or if educated outside the United States or trained in the United States military, graduated from an education program determined to be substantially equivalent to physical therapist assistant entry level education in the United States by a credentials evaluation organization approved by the American Physical Therapy Association or identified at 8 CFR 212.15(e); or

(2) Passed a national examination for physical therapist assistants on or before December 31, 2009, and meets one of the following:

(i) Is licensed, or otherwise regulated in the state in which practicing.

(ii) In states where licensure or other regulations do not apply, graduated before December 31, 2009, from a 2-year college-level program approved by the American Physical Therapy Association and after January 1, 2010, meets the requirements of paragraph (b)(8) of this section.

(iii) Before January 1, 2008, where licensure or other regulation does not apply, graduated from a 2-year college level program approved by the American Physical Therapy

Association.

(iv) On or before December 31, 1977, was licensed or qualified as a physical therapist assistant and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service.

(i) Standard: Physician. A person who meets the qualifications and conditions specified in section 1861(r) of the Act and implemented at §410.20(b) of this chapter.

(j) Standard: Registered nurse. A graduate of an approved school of professional nursing who is licensed in the state where practicing.

(k) Standard: Social work assistant. A person who provides services under the supervision of a qualified social worker and:

(1) Has a baccalaureate degree in social work, psychology, sociology, or other field related to social work, and has had at least 1 year of social work experience in a health care setting; or

(2) Has 2 years of appropriate experience as a social work assistant, and has achieved a satisfactory grade on a proficiency examination conducted, approved, or sponsored by the U.S. Public Health Service, except that the determinations of proficiency do not apply with respect to persons initially licensed by a state or seeking initial qualification as a social work assistant after December 31, 1977.

(l) Standard: Social worker. A person who has a master's or doctoral degree from a school of social work accredited by the Council on Social Work Education, and has 1 year of social work experience in a health care setting.

(m) Standard: Speech-language pathologist. A person who has a master's or

doctoral degree in speech-language pathology, and who meets either of the following requirements:

(1) Is licensed as a speech-language pathologist by the state in which the individual furnishes such services; or

(2) In the case of an individual who furnishes services in a state which does not license speech-language pathologists:

(i) Has successfully completed 350 clock hours of supervised clinical practicum (or is in the process of accumulating supervised clinical experience);

(ii) Performed not less than 9 months of supervised full-time speech-language pathology services after obtaining a master's or doctoral degree in speech-language pathology or a related field; and

(iii) Successfully completed a national examination in speech-language pathology approved by the Secretary.

PART 485 – CONDITIONS OF PARTICIPATION: SPECIALIZED PROVIDERS

8. The authority citation for part 485 continues to read as follows:

Authority: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395(hh)).

PART 488 -- SURVEY, CERTIFICATION, AND ENFORCEMENT PROCEDURES

9. The authority citation for part 488 continues to read as follows:

Authority: Secs. 1102, 1128I and 1871 of the Social Security Act, unless otherwise noted (42 U.S.C. 1302, 1320a-7j, and 1395hh); Pub. L. 110-149, 121 Stat. 1819.

10. In the table below, for each section and paragraph indicated in the first two

columns, remove the reference indicated in the third column and add the reference indicated in the fourth column:

Section	**Paragraphs**	**Remove**	**Add**
§485.58	Introductory text	484.4	484.115
§485.70	(c) and (e)	§484.4	§484.115
§488.805	Definition of “temporary management	§§484.4 and 484.14(c)	§§484.105(b) and 484.115

CMS-3819-P

Dated: June 17, 2014.

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Marilyn Tavenner,

Administrator,

Centers for Medicare & Medicaid Services.

Dated: July 11, 2014.

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Sylvia M. Burwell,

Secretary.

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